IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

IN RE
FACTOR VIII OR IX CONCENTRATE
BLOOD PRODUCTS LITIGATION

_____

MALKA ASHKENAZI, individually, as Personal Representative of the Estate of the Decedent ELI ASHKENAZI, as Guardian for the minor PLaintiff MOTI ASHKENASI, and HADAS ASHKENAZI (an adult child of the Decedent), all citizens of Israel,

Plaintiffs,

v.

BAYER CORPORATION, an Indiana corporation, successor to CUTTER BIOLOGICAL, a California Corporation; BAXTER HEALTHCARE CORPORATION, a Delaware corporation, and its HYLAND DIVISION; BAXTER INTERNATIONAL, INC., a Delaware corporation, successor to IMMUNO - U.S., INC., a Michigan Corporation; ARMOUR PHARMACEUTICAL COMPANY, INC., a Delaware corporation; and ALPHA THERAPEUTIC CORPORATION, a California corporation,

Defendants.

MDL No. 986 JFG
No. 1:93cv7452

THIS DOCUMENT
RELATES TO:
The Action Listed Below

CASE NO. 08-1767

E-FILED

ANSWER OF DEFENDANT BAYER CORPORATION TO FIRST AMENDED COMPLAINT FOR DAMAGES AND INJUNCTIVE RELIEF

JURY DEMAND

DISCLOSURE STATEMENT

Defendant BAYER CORPORATION (hereinafter referred to as "Bayer") objects to Plaintiffs' Complaint on the ground that this Complaint is not the short and plain statement of a claim required by Rule 8, of the Federal Rules of Civil Procedure. Many of the allegations are

vague, ambiguous and therefore objectionable, including, but not limited to, all allegations said to have occurred "at all pertinent times" which is not otherwise defined. Much of the Complaint consists of quotations from newspapers and other publications and documents. Bayer objects to having to guess at what allegations against Bayer, if any, Plaintiffs are making by quoting what others have written.

Without waiving any of the foregoing objections, even if not specifically repeated hereafter, defendant Bayer, in response to Plaintiffs' Complaint on file, answers each and every cause of action allegedly set forth therein, and admits, denies, and alleges as follows:

I. ANSWER TO PLAINTIFFS' INTRODUCTION

1. Defendants manufactured blood products known as "Factor VIII" and "Factor IX" for the treatment of hemophilia, and sold these products to people with hemophilia in Israel and other foreign markets, despite knowledge that the products were manufactured from sick, high risk donors and/or known to be contaminated with the viruses that cause the Human Immunodeficiency Virus and Hepatitis C (now known as "HIV" or "HIV/AIDS" and "HCV" respectively). Defendants continued selling these products to people with hemophilia in Israel and elsewhere even after the products were no longer being used in the United States due to the known risk of HIV/AIDS and HCV transmission. As discussed more fully in paragraphs 66 - 69, Defendants, such as BAXTER/IMMUNO and CUTTER refused to recall old stocks of products they knew to be contaminated with HIV and HCV both in the United States and abroad even after they had introduced a safer product.

First Defense

PARAGRAPH NO. 1 ANSWER: Bayer admits that, beginning in 1968, it or one of its predecessors was licensed by the Food and Drug Administration ("FDA") to process and

distribute Factor IX, and that, beginning in 1974, it or one of its predecessors was licensed by the FDA to process and distribute Factor VIII. Bayer further admits that treatment of hemophilia includes intravenous introduction of missing blood components essential for coagulation and that prevalent forms of such treatment include blood factor concentrates containing Factor VIII and Factor IX. Bayer further admits that it engaged in the collection of plasma and the processing and distribution of Factor VIII and Factor IX produced from such plasma and that Bayer processed plasma taken from human donors. Bayer denies all allegations in this and numerous subsequent paragraphs of the Complaint that Defendants "manufactured" or "sold" Factor VIII and Factor IX and denies that Factor VIII and Factor IX are "products." Except as admitted above, to the extent the matters set forth in Paragraph 1 are intended to constitute allegations of a defect, wrongdoing or a failure to exercise due care directed to Bayer and/or its predecessors, Bayer denies them. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 1 of the Complaint.

2. Plaintiffs' decedent, ELI ASHKENAZI ("Decedent") had hemophilia, resided in Israel, and contracted HIV and HCV through use of Defendants' contaminated products. Further, Defendants, such as BAXTER/IMMUNO and CUTTER allowed their untreated factor concentrate products to remain on the market in Israel for years after they were required to begin providing safer, treated factor concentrate products in the United States.

PARAGRAPH NO. 2 ANSWER: Bayer denies that Cutter Biological distributed factor concentrates to Israel. To the extent the matters set forth in Paragraph 2 are intended to constitute allegations of a defect, wrongdoing or a failure to exercise due care directed to Bayer and/or its predecessors, Bayer denies them. Bayer is without knowledge or information

sufficient to form a belief as to the truth of any remaining allegations in Paragraph 2 of the Complaint.

3. Defendants manufactured HIV and HCV-contaminated blood factor products at plants in the United States using human plasma taken from thousands of paid American donors, including populations then known to be at high risk of carrying blood-borne diseases, such as urban homosexuals, prisoners, and intravenous drug users. Defendants intentionally recruited urban homosexuals who had a history of viral hepatitis as plasma donors, despite regulations prohibiting the use of such donors and despite knowledge that the viruses that cause HIV/AIDS and HCV were blood-borne diseases prevalent in such populations. Defendants continued using plasma taken from high risk prison donors, including from prisoners at the notorious Angola prison in Louisiana, even after promising the FDA that they would cease doing so. Through their trade associations, Defendants actively conspired to conceal these practices and to substantially delay product recalls and implementation of safety measures.

PARAGRAPH NO. 3 ANSWER: Bayer admits that it processed, in facilities in the United States, plasma taken from human donors who were compensated for their time and distributed Factor VIII and Factor IX for the treatment of hemophilia. Bayer admits that thousands of such donors were required to meet the medical needs for Factor VIII and Factor IX. Except as admitted above, to the extent the matters set forth in Paragraph 3 are intended to constitute allegations of a defect, wrongdoing or a failure to exercise due care directed at Bayer and/or its predecessors, Bayer denies them. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 3 of the Complaint.

4. Defendants failed to fully and completely disclose the known risks of their products,

including the risk of HIV/AIDS and HCV; failed to implement readily available screening tests that would have prevented HIV/AIDS and HCV by excluding contaminated plasma; failed to use available methods of treating plasma to kill viruses, including heat treatment and solvent detergent; and concealed and affirmatively misrepresented the extent of the health dangers of the diseases caused by the products. Defendants continued to ship non-heat treated product to Israel and other foreign markets even after ceasing to sell it in the United States, in order to maintain their profit margin on existing contracts and sell off remaining stock no longer marketable domestically. Defendants also continued to sell old stocks of product that had not been treated with solvent detergent both in the United States and abroad, even after introducing a safer product treated with solvent detergent, including stocks that Defendants knew or had reason to know were made from pooled blood contaminated with HIV and HCV.

PARAGRAPH NO. 4 ANSWER: Bayer denies the allegations in the first sentence of Paragraph 4 of the Complaint. To the extent they are directed to Bayer and/or its predecessors, Bayer denies any remaining allegations in Paragraph 4 of the Complaint. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 4 of the Complaint.

5. Defendants' efforts to maximize profits came at the expense of the health and lives of thousands of people with hemophilia in Israel and elsewhere who were needlessly infected with HIV/AIDS and HCV, including Plaintiffs' Decedent.

PARAGRAPH NO. 5 ANSWER: Bayer denies the allegations in Paragraph 5 of the Complaint.

II. ANSWER TO ALLEGATIONS REGARDING JURISDICTION AND VENUE

6. Plaintiffs allege an amount in controversy in excess of $75,000, exclusive of interest and costs. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332 because there is complete diversity of citizenship between the Plaintiffs and the Defendants.

PARAGRAPH NO. 6 ANSWER: Bayer admits that the Complaint purports to commence an action for certain damages. Bayer denies that it is liable to Plaintiffs for any damages and denies that Plaintiffs are entitled to any relief against Bayer as requested in the Complaint. If the Plaintiffs are, as they appear to allege, citizens of Israel, Bayer admits that there is complete diversity of citizenship and therefore this Court has jurisdiction under 28 U.S.C. § 1332.

7. Pursuant to this Court's prior Order (attached here to as Exhibit A), this action should be administratively transferred to MDL 986, pending before the Honorable John F. Grady, since it involves allegations of injuries and damages including HIV, HCV and related complications and injuries as a result of exposure to Defendants' blood factor products.

PARAGRAPH NO. 7 ANSWER: Bayer admits that this action should be administratively transferred to the Honorable John F. Grady because the Complaint contains allegations that are similar to allegations in other cases pending before him as part of or in connection with MDL-986. Bayer denies that it is liable to Plaintiffs for any damages and denies that Plaintiffs are entitled to any relief against Bayer.

8. Plaintiffs are informed and believe and upon such information and belief allege that the unlawful, negligent and/or tortious activity alleged herein was carried out predominantly in the United States. Defendants recruited high risk paid donors in the United States and mixed plasma from such donors into the blood pool at their facilities in the United States. Defendants

placed misleading labels on their products in the United States and made affirmative misrepresentations regarding their products' safety in the United States, which were relied upon by Plaintiffs and their medical providers. Defendants' decisions to recruit paid donors from high risk populations, to refrain from disclosing the known risks of their products, to forego implementing readily available procedures that would have prevented their products from transmitting HIV/AIDS and HCV, and to ship their products to Israel and other foreign markets even after they could no longer be used domestically were all made in the United States. Defendants' acts of conspiracy, including trade association meetings where they agreed to engage in wrongful conduct, also took place in the United States.

PARAGRAPH NO. 8 ANSWER: Bayer denies any unlawful activity and therefore denies the allegations in Paragraph 8 of the Complaint.

9. Plaintiffs are informed and believe and upon such information and belief allege that the vast majority of the evidence of the unlawful activity alleged herein is located in the United States. Documents showing Defendants' policies, practices, and decisions regarding recruitment of plasma donors, mixing of plasma into the blood pool at their facilities, labeling of their products, advertising and promotion of their products, disclosure or lack thereof of the risks posed by their products, implementation or lack thereof of procedures to prevent their products from transmitting HIV/AIDS and HCV, and shipment of their products to Israel and other foreign markets are located almost exclusively in the United States. The vast majority of witnesses who will testify to these policies, practices, and decisions are also located in the United States, and would not be subject to subpoena in other countries. The expert witnesses likely to be presented by both Plaintiffs and Defendants are also located in the United States.

PARAGRAPH NO. 9 ANSWER: Bayer denies the allegations in the first sentence of Paragraph 9 of the Complaint. To the extent they are directed to Bayer and/or its predecessors, Bayer denies any remaining allegations in Paragraph 9 of the Complaint. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 9 of the Complaint.

10. Most of the relevant medical records regarding the claims of Plaintiffs are located in the United States or have already been brought to the United States and have already been produced to Defendants. Similarly, Plaintiffs have produced or are in the process of preparing for production in the United States Preliminary Patient Profile Forms ("PPPFs"). In addition, witnesses to the Plaintiffs' damages, such as the Plaintiffs' family members, are willing to travel to the United States to testify.

PARAGRAPH NO. 10 ANSWER: Bayer admits that some Plaintiffs have produced PPFs. Bayer denies that Plaintiffs are entitled to damages. Except as admitted or denied above, Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 10 of the Complaint.

11. Because the Plaintiffs in this action reside in Israel with a different legal system, litigation in their home country would be costly and inefficient. In addition, Israel is an inadequate alternative forum because of chronic and lengthy court delays, lack of open discovery, unavailability of legal theories, procedures, and remedies, and lack of subpoena power over physical evidence in the United States.

PARAGRAPH NO. 11 ANSWER: Bayer denies the allegations in Paragraph 11 of the Complaint.

12. Plaintiffs are informed and believe and upon such information and belief allege that

Defendants' unlawful activity was carried out largely in the United States, and, in significant part, in the Northern District of Illinois. Defendant ARMOUR PHARMACEUTICAL COMPANY had its only blood factor manufacturing and processing plant in Kankakee, Illinois, at all pertinent times. This plant was the location of many meetings regarding the processing and research and development of factor concentrates, including meetings in the early 1980s involving discussions about the possible use of solvent detergents in the manufacturing of blood factor concentrates. This plant was also the location of inspections by the United States Food and Drug Administration and Canadian authorities amid reports of viral infections being spread through the use of factor concentrates. In addition, at all times pertinent, ARMOUR PHARMACEUTICAL COMPANY had subsidiary Collection Centers, collecting blood from paid donors, in Illinois.

PARAGRAPH NO. 12 ANSWER: Bayer denies any unlawful activity and therefore denies the allegations in the first sentence of Paragraph 12 of the Complaint. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 12 of the Complaint.

13. Defendants BAXTER HEALTHCARE CORPORATION ("BAXTER HEALTHCARE"), BAXTER INTERNATIONAL, INC. ("BAXTER INTERNATIONAL") and IMMUNO U.S., Inc. ("IMMUNO U.S.") had their headquarters in Illinois at all pertinent times. Defendant BAXTER HEALTHCARE also collected blood from donors in Illinois at all times pertinent, including from donors jailed in the Cook County Jail in the early 1980s.

PARAGRAPH NO. 13 ANSWER: Bayer is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 13 of the Complaint.

14. Plaintiffs are informed and believe and upon such information and belief allege that considerable evidence of Defendants' unlawful activity is located, in significant part, in the Northern

District of Illinois, where much of the unlawful activity was carried out.

PARAGRAPH NO. 14 ANSWER: Bayer denies any unlawful activity and therefore denies the allegations in Paragraph 14 of the Complaint.

15. Plaintiffs are informed and believe and on such information and belief allege that the conduct by Defendants that is relevant to the subject matter of this action took place primarily in their respective headquarters locations, or in other facilities within the States of Illinois and California giving these states significant contacts to the claims asserted by Plaintiffs and creating state interests such that the choice of either or each of these states' laws to govern the adjudication of this action is neither arbitrary nor fundamentally unfair, and Plaintiffs hereby consent thereto.

PARAGRAPH NO. 15 ANSWER: The allegations in Paragraph 15 of the Complaint set forth conclusions of law to which no response is required. To the extent that a response is required and to the extent they are directed to Bayer and/or its predecessors, Bayer denies the allegations in Paragraph 15 of the Complaint. To the extent that a response is required, Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 15 of the Complaint.

III. ANSWER TO ALLEGATIONS REGARDING PARTIES

16. The Plaintiffs in this action are as follows:

PARAGRAPH NO. 16 ANSWER: Paragraph 16 of the Complaint is merely introductory and therefore no response is required.

17. Plaintiff MALKA ASHKENAZI, the surviving spouse of Decedent Eli Ashkenazi, who was a resident of Ness Ziona, Israel, and who had hemophilia, and who was infected with HIV and HCV as a result of infusing Defendants' contaminated factor concentrate and/or as a result of Defendants' conspiracy. Plaintiff's Decedent has already provided Defendants with a confidential

Preliminary Patient Profile Form (PPF), with beginning Bates number L-PPF 00485; the PPF contains substantial additional information regarding Plaintiff's claim. Plaintiff MALKA ASHKENAZI resides in and is a citizen of Israel.

PARAGRAPH NO. 17 ANSWER: Bayer denies that it injured Plaintiff. Bayer denies that it or any of its predecessors were parties to any conspiracy. Bayer admits that Plaintiff has provided a confidential PPF, with beginning Bates number L-PPF 004858, which purports to provide certain information regarding Plaintiff. Except as admitted or denied above, to the extent matters set forth in Paragraph 17 are intended to constitute allegations of a defect, wrongdoing or a failure to exercise due care directed at Bayer and/or its predecessors, Bayer denies them. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 17 of the Complaint.

18. Plaintiff MOTI ASHKENAZI is the minor child of the Decedent, and resides in and is a citizen of Israel. Plaintiff MALKA ASHKENAZI is the lawful Guardian of the minor Plaintiff MOTI ASHKENAZI.

PARAGRAPH NO. 18 ANSWER: Bayer is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 18 of the Complaint.

19. Plaintiff HADAS ASHKENAZI is the adult child of the Decedent, and resides in and is a citizen of Israel.

PARAGRAPH NO. 19 ANSWER: Bayer is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 19 of the Complaint.

20. The Plaintiff’s Decedent, Eli Ashkenazi, was the beloved husband and father of the Plaintiffs and died on or about March 31, 2007, in Israel, as a direct and proximate result of use of Defendants’ blood products and Defendants’ conspiracy. The Decedent resided in and

was a citizen of Israel. (Decedent's Death Certificate, the Declarations of Professor Daniel More, Advocate Chen Varshaviak, and Plaintiff Malka Ashkenazi, and the corresponding translator's Certificates of Accuracy, are attached hereto as Exhibit B.)

PARAGRAPH NO. 20 ANSWER: To the extent any matters set forth in Paragraph 20 are intended to constitute allegations of a defect, wrongdoing or a failure to exercise due care directed at Bayer and/or its predecessors, Bayer denies them. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 20 of the Complaint.

21. Plaintiff's Decedent contracted permanent injuries and diseases, including HIV/AIDS and HCV and associated symptoms and diseases, as a direct and proximate result of use of Defendants' blood products and Defendants' conspiracy.

PARAGRAPH NO. 21 ANSWER: Bayer denies the allegations in Paragraph 21 of the Complaint.

22. Plaintiff's Decedent would not have chosen to be treated with Defendants' blood products had he known of or been informed by Defendants of the true risks of using those products or the nature of the sources of the blood products.

PARAGRAPH NO. 22 ANSWER: Bayer denies that it failed to advise of the risks of its Factor VIII and Factor IX. To the extent any remaining matters set forth in Paragraph 22 are intended to constitute allegations of a defect, wrongdoing or a failure to exercise due care directed at Bayer and/or its predecessors, Bayer denies them. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 22 of the Complaint.

23. CUTTER, the predecessor of Miles, Inc. and Defendant BAYER, was a California

corporation headquartered in Berkeley, California at all pertinent times. CUTTER was at all pertinent times a citizen of California. At all pertinent times CUTTER and its successors Miles, Inc. and BAYER regularly and systematically engaged in the harvesting and collection of human plasma and the processing, manufacturing, marketing, sales and distribution of anti-hemophilic factor (hereinafter referred to as "AHF") produced from such plasma, to which Plaintiffs' Decedent was exposed and which contributed directly or indirectly to Plaintiffs' Decedent's infection with HIV and HCV.

PARAGRAPH NO. 23 ANSWER: Bayer admits that Cutter Laboratories, Inc. was a corporation with its headquarters in Berkeley, California until it ceased to exist as a separate corporation on January 1, 1983, and that Cutter was a predecessor of Miles, Inc. and a predecessor of Bayer. Bayer admits that it engaged in the collection of plasma and the processing and distribution of Factor VIII and Factor IX produced from such plasma. Bayer denies the remaining allegations in Paragraph 23 of the Complaint.

24. Defendant BAYER, formerly Miles, Inc., is and was an Indiana corporation, authorized to do business in all 50 states and the District of Columbia. Miles, Inc. had its principal place of business operation in Elkhart, Indiana, while its successor BAYER has its principal place of business in Pennsylvania, with offices located at 100 Bayer Road, Pittsburgh, Pennsylvania 15205. Defendant BAYER, at all pertinent times, is and was a citizen of Indiana and Pennsylvania. At all pertinent times BAYER and its predecessors Miles, Inc., and CUTTER regularly and systematically engaged in the harvesting and collection of human plasma and the processing, manufacturing, marketing, sales and distribution of anti-hemophilic factor (hereinafter referred to as "AHF") produced from such plasma, to which Plaintiffs' Decedent was exposed and which contributed directly or indirectly to Plaintiffs' Decedent's infection with HIV and HCV.

PARAGRAPH NO. 24 ANSWER: Bayer admits that it is a corporation organized and existing under the laws of the State of Indiana with its principal place of business in Pittsburgh, Pennsylvania, with offices located at 100 Bayer Road, Pittsburgh, Pennsylvania, and is and was authorized to do business in all fifty states, including the State of Illinois. Bayer further admits that Miles, Inc. had its headquarters in Elkhart, Indiana. Bayer admits that it engaged in the collection of plasma and the processing and distribution of Factor VIII and Factor IX produced from such plasma. Bayer denies the remaining allegations in Paragraph 24 of the Complaint.

25. Defendant BAXTER HEALTHCARE is a Delaware corporation, authorized to do business in all 50 states and the District of Columbia, with its principal place of business in Illinois, with offices located at One Baxter Parkway, Deerfield, Illinois 60015. At all times pertinent, Defendant BAXTER HEALTHCARE, and/or its HYLAND DIVISION, had its main manufacturing plant in Glendale, California. Defendant BAXTER HEALTHCARE, at all pertinent times, is and was a citizen of Delaware and Illinois. At all times pertinent, Defendant BAXTER HEALTHCARE, and/or its HYLAND DIVISION, and/or its wholly owned subsidiaries Travenol Laboratories and Fenwal Laboratories, regularly and systematically engaged in the harvesting and collection of human plasma and the processing, manufacturing, marketing, sales and distribution of AHF products produced from such plasma, which contributed directly or indirectly to Plaintiffs' Decedent's infection with HIV and/or HCV.

PARAGRAPH NO. 25 ANSWER: Upon information and belief, Bayer admits that Baxter Healthcare Corporation is a Delaware corporation with its principal place of business in Illinois. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 25 of the Complaint.

26. Defendant BAXTER INTERNATIONAL is a Delaware Corporation, and owner and

successor in interest to Immuno International A.G., and IMMUNO-U.S. (described hereinafter collectively as, "IMMUNO"). BAXTER INTERNATIONAL has its principal place of business in Illinois, with offices located at One Baxter Parkway, Deerfield, Illinois 60015, and, on information and belief, is the party liable for the injuries resulting from infusion with Immuno factor concentrates during the relevant period. Defendant BAXTER INTERNATIONAL, at all pertinent times, is and was a citizen of Delaware and Illinois.

PARAGRAPH NO. 26 ANSWER: Upon information and belief, Bayer admits that Baxter International Corporation is a Delaware corporation with its principal place of business in Illinois. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 26 of the Complaint.

27. In 1997, BAXTER INTERNATIONAL acquired all assets and liabilities of Immuno International A.G., an Austrian company that at all times pertinent sold AHF products to Israel and other foreign markets that were produced from human plasma derived from paid donors in the United States. Immuno International A.G. operated in the United States at all times pertinent through its wholly owned American subsidiary Immuno-U.S., located in Rochester, New York. IMMUNO operated 15 processing centers in the United States in the 1980s, which collected plasma from high-risk donors for fractionation in plants located in Rochester, Michigan and Vienna, Austria. These products were then shipped all over the world, and contributed directly or indirectly to Plaintiffs' infection with HIV and HCV. IMMUNO's product names, Bebulin, Feiba, and Prothromplex, are now listed as BAXTER INTERNATIONAL products in the 2003 Registry of Factor Concentrates put out by the World Federation for Hemophilia.

PARAGRAPH NO. 26 ANSWER: Bayer is without knowledge or information sufficient to form a belief as to the truth of any allegations in Paragraph 26 of the Complaint.

28. IMMUNO – U.S. was a Michigan corporation and was at all pertinent times a United States based operating subsidiary of Immuno International A.G. The most recent corporate filing for IMMUNO – U.S. is the 1998 certificate of merger filed by BAXTER, listing the principal place of business for the surviving entity as One Baxter Parkway, Deerfield, IL 60015, the same address for Defendants BAXTER INTERNATIONAL and BAXTER HEALTHCARE.

PARAGRAPH NO. 28 ANSWER: Upon information and belief, Bayer admits that Immuno-U.S. is a Michigan corporation. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 28 of the Complaint.

29. Defendant ARMOUR PHARMACEUTICAL COMPANY, INC. (described hereinafter as "ARMOUR"), is a Delaware corporation, authorized to do business in all 50 states and the District of Columbia, with its principal place of business in Pennsylvania, with offices located at 500 Arcola Road, P.O. Box 1200, Collegeville, Pennsylvania 19426-0107. Defendant ARMOUR at all pertinent times, is and was a citizen of Delaware and Pennsylvania. Defendant ARMOUR sold AHF products which were produced from human plasma derived from paid donors in the United States. ARMOUR regularly and systematically engaged in the harvesting and collection of human plasma and the processing, manufacturing, marketing, sales and distribution of AHF products produced from such plasma, to which Plaintiffs' Decedent was exposed and which contributed directly or indirectly to Plaintiffs' Decedent's infection with HIV and/or HCV.

PARAGRAPH NO. 29 ANSWER: Upon information and belief, Bayer admits that an entity named Armour Pharmaceutical Company is a Delaware corporation with its principal place of business in New Jersey. Upon information and belief, Bayer admits that Aventis Behring LLC is a Delaware limited liability company with its principal place of business in Pennsylvania. Upon information and belief, Bayer admits that Aventis Inc. is a Delaware

corporation with its principal place of business in New Jersey. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 29 of the Complaint.

30. Defendant ALPHA THERAPEUTIC CORPORATION (hereinafter "ALPHA") is a California corporation authorized to do business in all 50 states and the District of Columbia, with its principal place of business in California, with offices at 5555 Valley Boulevard, Los Angeles, California 90032. Defendant ALPHA, at all pertinent times, is and was a citizen of California. At all times pertinent Defendant ALPHA has been regularly and systematically engaged in the harvesting and collection of human plasma and the processing, manufacturing, marketing, sales and distribution of AHF products produced from such plasma, to which Plaintiffs were exposed and which contributed directly or indirectly to Plaintiffs' Decedent's infection with HIV and HCV.

PARAGRAPH NO. 30 ANSWER: Upon information and belief, Bayer admits that Alpha Therapeutic Corporation is a California corporation with its principal place of business in California. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 30 of the Complaint.

31. Defendants BAYER, ARMOUR, BAXTER HEALTHCARE, BAXTER INTERNATIONAL and ALPHA (herein collectively identified as "MANUFACTURERS" or "DEFENDANTS") acting on behalf of themselves and/or their predecessor and/or successor corporations, collected, harvested and/or processed human plasma and/or manufactured, marketed, sold and distributed factor concentrate products to Israel and other foreign markets that were contaminated with HIV/AIDS and/or HCV. In the alternative, one or more of said Defendants participated in the collection, harvesting and/or processing of human plasma and/or the manufacturing, marketing, distribution and sale of factor concentrate products to Israel and other

foreign markets, or assumed, became or are responsible for the liabilities of the Defendants and their predecessor or successor corporations who did participate in the collection, harvesting and/or processing of human plasma and/or the manufacturing, marketing, distribution or sale of factor concentrate products to Israel and other foreign markets, without limitation thereto.

PARAGRAPH NO. 31 ANSWER: Bayer admits that Cutter engaged in the collection and processing of human plasma and the distribution of Factor VIII and Factor IX concentrate in the United States and in foreign countries. Except as admitted above, to the extent the matters set forth in Paragraph 31 are intended to constitute allegations of a defect, wrongdoing or a failure to exercise good care directed to Bayer and/or its predecessors, Bayer denies them. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 31 of the Complaint.

32. At all times herein mentioned, all Defendants and each of them, were fully informed of the actions of their agents and employees, and thereafter no officer, director or managing agent of Defendants repudiated those actions, which failure to repudiate constituted adoption and approval of said actions and that all Defendants and each of them, thereby ratified those actions.

PARAGRAPH NO. 32 ANSWER: The allegations in Paragraph 32 of the Complaint set forth conclusions of law to which no response is required. To the extent a response is required, and to the extent they are directed to Bayer and/or its predecessors, Bayer denies the allegations in Paragraph 32 of the Complaint. To the extent that a response is required, Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 32 of the Complaint.

IV. ANSWER TO PLAINTIFF'S "FACTUAL ALLEGATIONS" APPLICABLE TO ALL CLAIMS

A. Answer to Allegations Regarding Hemophilia and Its Treatment

33. Hemophilia is an inherited condition that causes uncontrolled hemorrhaging or bleeding. Hemophilia results from a deficiency of blood components essential for coagulation. The most common form of the disease is hemophilia A, characterized by a lack of a blood protein known as Factor VIII, which affects approximately one in 10,000 males. Factor VIII is commonly called "AHF," or anti-hemophilic factor. Hemophilia B is characterized by absence of another blood protein, known as Factor IX, affecting about one in 40,000 males. Von Willebrand's disease is an inherited hemorrhagic condition similar to hemophilia that affects both men and women. It is characterized by lack of both Factor VIII and another blood protein called von Willebrand's factor.

PARAGRAPH NO. 33 ANSWER: Bayer admits that hemophilia is a fairly rare disorder present from birth in which the affected person is unable to produce adequate levels necessary for normal clotting of one or more proteins in the blood known as factors. Bayer admits that a deficiency of Factor VIII, known as hemophilia A, is the most prevalent form of the illness and a deficiency of Factor IX is known as hemophilia B. Bayer admits that Factor VIII concentrates are commonly called "AHF." Bayer admits that von Willebrand's disease is a bleeding disorder that affects both men and women. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 33 of the Complaint.

34. The treatment of hemophilia and von Willebrand's disease involves intravenous introduction, called infusion, of the missing blood proteins required to stop bleeding. The two most prevalent forms of such treatment are cryoprecipitate, and factor concentrates. Factor concentrates are the product made by Defendants in this action. Cryoprecipitate is made by freezing plasma, the

fluid component of circulating blood in which various proteins, including Factor VIII and Factor IX, are contained; thawing the frozen plasma; and isolating Factor VIII from the plasma through centrifugal concentration. Cryoprecipitate is an effective therapeutic agent for patients with hemophilia A. Hemophilia B has been effectively treated with the use of fresh frozen plasma containing Factor IX. Cryoprecipitate and fresh frozen plasma are made from small numbers of donors, who are generally unpaid volunteers.

PARAGRAPH NO. 34 ANSWER: Bayer admits hemophilia is a fairly rare disorder present from birth in which the affected person is unable to produce adequate levels necessary for normal clotting, of one or more proteins in the blood known as "factors." Bayer admits that factor concentrates are produced by a process consisting of several steps known collectively as "fractionation." Bayer denies that Factor VIII or Factor IX are products. Bayer admits that treatment of hemophilia can include intravenous introduction of missing blood components essential for coagulation (sometimes referred to as "infusion") and that prevalent forms of such treatment include blood factor concentrates and cryoprecipitate. Bayer admits that cryoprecipitate results from the freezing and thawing of human plasma which results in a material rich in Factor VIII and that cryoprecipitate is used to treat hemophilia A. Bayer admits that fresh frozen plasma contains some Factor IX and has been used to treat hemophilia B. Except as admitted or denied above, Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 34 of the Complaint.

35. By contrast, Defendants in the late 1960s to early 1970s began to market factor concentrates, or AHF, which contained Factor VIII and Factor IX in higher concentrations than had been available in either cryoprecipitate or fresh-frozen plasma. To produce factor concentrates, Defendants mixed pools of plasma from five to twenty thousand donors at a time, a substantial

percentage of which were paid donors. These large pools were then subjected to chemical process to concentrate Factors VIII and IX.

PARAGRAPH NO. 35 ANSWER: Bayer admits that, beginning in 1968, it or one of its predecessors was licensed by the FDA to process and distribute Factor IX, and that, beginning in 1974, it or one of its predecessors was licensed by the FDA to process and distribute Factor VIII. Bayer admits that its Factor VIII concentrate contained higher concentrations of that protein than cryoprecipitate and that Factor VIII and Factor IX concentrate contained higher concentrations of these proteins than fresh frozen plasma. Cryoprecipitate does not contain Factor IX. Bayer admits that it processed plasma taken from human donors, some of whom were compensated for their time, and that their plasma was combined into "pools" and subject to a process, consisting of several steps, involving chemicals and other actions, known collectively as "fractionation" which had the effect of producing a more concentrated form of Factor VIII and Factor IX. Except as admitted above, to the extent the matters set forth in Paragraph 35 are intended to constitute allegations of a defect, wrongdoing or a failure to exercise due care directed to Bayer and/or its predecessors, Bayer denies them. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 35 of the Complaint.

B. Answer to Allegations Regarding Failure to Disclose or Warn

36. Shortly after the initial commercial marketing of Factor VIII and IX concentrates in the late 1960s to early 1970s, a wide range of serious adverse effects were reported in association with these products. Even before the dissemination of HIV, Defendants knew of serious diseases caused by unidentified agents transmissible by blood and Factor VIII and IX. Defendants failed to warn Plaintiffs, Plaintiffs' Decedent or the medical community of these

adverse effects, in violation of industry standards and federal regulations.

PARAGRAPH NO. 36 ANSWER: Bayer admits that, in the late 1960's and early 1970's, the use of factor concentrates was known to cause adverse effects. Except as admitted above, Bayer denies the remaining allegations in Paragraph 36 of the Complaint.

37. By 1976, only a few years after Defendants' factor concentrate products went on the market, the United States Food and Drug Administration ("FDA") Bureau of Biologics held a conference entitled "Unsolved Therapeutic Problems in Hemophilia." The research articles compiled from the conference discussed the high incidence in patients using Defendants' products of disorders such as liver dysfunction, enlarged spleen, Hepatitis B, and Non-A, Non-B Hepatitis ("NANB Hepatitis," later renamed Hepatitis C). The articles concluded that these disorders were tied to the patients' use of factor concentrates, and emphasized the risks entailed in producing such concentrates using plasma from paid donors. As described below, however, Defendants not only refused to implement such a voluntary donor system, but instead recruited paid donors precisely because their hepatitis exposure resulted in plasma from which Defendants could make other commercially valuable products as well.

PARAGRAPH NO. 37 ANSWER: The allegations in Paragraph 37 of the Complaint refer to a conference and purport to characterize certain articles allegedly compiled from that conference. Those articles are in writing and speak for themselves. To the extent that Plaintiffs' allegations regarding the content of those articles are inconsistent with the actual language of the articles or are intended to constitute allegations of a defect, wrongdoing or a failure to exercise due care directed to Bayer and/or its predecessors, Bayer denies them. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 37 of the Complaint.

38. Several of the articles from the 1976 conference also raised alarm over the unprecedented convergence of immune disorders in the hemophiliac community, and called for close medical monitoring of the situation.

PARAGRAPH NO. 38 ANSWER: The allegations in Paragraph 38 of the Complaint refer to a conference and purport to characterize certain articles allegedly compiled from that conference. Those articles are in writing and speak for themselves. To the extent that Plaintiffs' allegations regarding the content of those articles are inconsistent with the actual language of the articles or are intended to constitute allegations of a defect, wrongdoing or a failure to exercise due care directed to Bayer and/or its predecessors, Bayer denies them.

39. At all times material to this Complaint, Defendants failed to adequately warn Plaintiffs, Plaintiffs' Decedent, or his physicians of these serious adverse side effects. Several such adverse effects, including immunosuppression (suppression of the immune system) were not mentioned at all in the Defendants' package inserts, which were required to disclose adverse reactions pursuant to federal statutes and regulations and applicable standards of care. Although Defendants' inserts mentioned a risk that plasma "may" contain the causative agent of viral hepatitis, the warning was seriously deficient in that: (a) Defendants failed to disclose that the risk of hepatitis was essentially a 100% guarantee due to their practices of using high-risk donors and specifically recruiting for donors who had previously been exposed to Hepatitis B; (b) while "hepatitis" simply means inflammation of the liver, and may be a relatively benign, temporary condition, Defendants failed to warn that some forms of hepatitis transmitted by their products were believed to present a considerable risk of severe liver damage, cirrhosis, and significantly elevated risk of cancer; (c) Defendants misleadingly stated that the source plasma used in preparation of the product had been found to be non-reactive for Hepatitis B surface antigen (HBsAg)—implying that no viral hepatitis

was present in the plasma—and falsely stated that available methods were not sensitive enough to detect all units of potentially infectious plasma, while failing to disclose that Defendants had refused to implement the more sophisticated Hepatitis B Core Antibody (HBc) test which would have excluded essentially all plasma contaminated by Hepatitis B; and (d) Defendants' labeling disclosed that the product was made from large pools of fresh human plasma, but failed to disclose that paid donors increased the risk of disease, and that the particular groups of paid donors targeted by Defendants were known to be the highest risk groups available.

PARAGRAPH NO. 39 ANSWER: To the extent the matters set forth in Paragraph 39 are intended to constitute allegations of a defect, wrongdoing or a failure to exercise due care directed to Bayer and/or its predecessors, Bayer denies them. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 39 of the Complaint.

C. Answer to Allegations Regarding Donor Recruitment

40. The demand for and supply of anti-hemophilia factor rapidly increased during the 1970's, with the commercially-manufactured concentrate accounting for a large proportion of the increase in supply. In 1977, a federal report projected that the volume of AHF manufactured would increase substantially by 1980. ("Study to Evaluate the Supply-Demand Relationships for AHF and PTC Through 1980," Division of Blood Diseases and Resources, National Heart, Lung and Blood Institute (1977), at page 8; hereinafter "NHLBI Report").

PARAGRAPH NO. 40 ANSWER: Bayer is without knowledge or information sufficient to form a belief as to the truth of the allegations in the first sentence in Paragraph 40 of the Complaint. The allegations in the second sentence in Paragraph 40 of the Complaint purport to refer to, or describe a NHLBI report. Such report is in writing and speaks for itself. To the

extent the allegations in the second sentence in Paragraph 40 are inconsistent with the NHLBI report, or are intended to constitute allegations of a defect, wrongdoing or a failure to exercise due care directed to Bayer and/or its predecessors, Bayer denies them.

41. In order to sell more AHF to this growing market, Defendants turned to the fastest and cheapest way of obtaining sufficient plasma, paid donors. Defendants recruited paid donors from those populations most likely to respond to the financial incentive to donate: poor inner city residents, drug abusers, prisoners, and even residents of impoverished developing countries such as Haiti and Nicaragua.

PARAGRAPH NO. 41 ANSWER: Bayer denies the allegations in Paragraph 41 of the Complaint.

42. Defendants purposefully sought out paid donors despite knowing that the risk of diseases transmissible by blood was far greater among paid donors than among volunteers. Because no test was available yet for the NANB Hepatitis virus identified in the early 1970's, the only means to prevent the virus from contaminating the plasma supply was to exclude donors with behaviors that were inconsistent with good health—precisely those populations from which Defendants were recruiting paid donors. Some studies indicated that paid donors were up to ten times more infectious than volunteer donors. For this reason, the National Blood Policy, adopted by the federal government in July 1973, advocated conversion to an all-volunteer blood supply. Defendants, however, not only continued to use paid donors, but also focused their recruiting efforts on the highest risk populations.

PARAGRAPH NO. 42 ANSWER: Bayer denies the allegations in Paragraph 42 of the Complaint.

43. Defendants had an additional financial incentive for recruiting paid donors. Factor VIII and Factor IX are only two of many products that can be made for commercial sale from human

plasma. According to the NHLBI Report, by the late 1970s at least 17 different therapeutic components of blood were manufactured by the process of "fractionating" plasma into its various elements. The NHLBI Report noted that, "as the costs of fractionation have increased, fractionators have produced as many products as possible from a liter of plasma." (Id. at 65).

PARAGRAPH NO. 43 ANSWER: The phrase "an additional financial incentive" is not a plain statement to which Bayer can or is required to respond. Bayer admits that therapeutic medication, in addition to Factor VIII and Factor IX, can sometimes be derived from the same unit of plasma. Except as admitted above, to the extent the matters set forth in Paragraph 43 are intended to constitute allegations of a defect, wrongdoing or a failure to exercise due care directed at Bayer and/or its predecessors, Bayer denies them. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in the first and second sentences of Paragraph 43 of the Complaint. The allegations in the third and fourth sentences in Paragraph 43 of the Complaint purport to refer to or describe a NHLBI report. Such report is in writing and speaks for itself. To the extent the allegations in the third and fourth sentences of Paragraph 43 are inconsistent with the NHLBI report, or are intended to constitute allegations of a defect, wrongdoing or a failure to exercise due care directed to Bayer and/or its predecessors, Bayer denies them.

44. Blood derivatives used as vaccines or therapeutics had particularly high economic value for Defendants. The NHLBI Report noted that plasma with a very high titer, or antibody level, for a corresponding antigen is "very expensive." (Id. at 41). Such products are manufactured from source plasma drawn from donors who have been sensitized to a particular antigen. (Id.). The NHLBI Report specifically stated, however, that "plasma collected for high antibody titer cannot be used for fractionation into therapeutic products," such as Defendants' factor concentrate. (Id., emphasis

added).

PARAGRAPH NO. 44 ANSWER: The phrase "particularly high economic value" is not a plain statement to which Bayer can or is required to respond. The allegations in the remainder of Paragraph 44 of the Complaint purport to refer to or describe a NHLBI report. Such report is in writing and speaks for itself. To the extent the allegations the remainder of Paragraph 44 are inconsistent with the NHLBI report, or are intended to constitute allegations of a defect, wrongdoing or a failure to exercise due care directed to Bayer and/or its predecessors, Bayer denies them. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 44 of the Complaint.

45. Defendants targeted donors with high titers to Hepatitis B antigens in order to manufacture and sell Hepatitis B immunoglobulin (HBIG), a product that confers temporary immunity to the Hepatitis B virus. Despite the warning in the NHLBI report, Defendants' used the same high titer plasma they obtained for making HBIG to manufacture the Factor VIII and IX products used by people with hemophilia. Defendants thus sought to maximize profits by producing "as many products as possible from a liter of plasma," while ignoring industry standards that precluded the use of high-titer plasma for other therapeutic products.

PARAGRAPH NO. 45 ANSWER: Bayer admits that HBIG confers temporary immunity to the Hepatitis B virus. Bayer denies that it manufactured or sold Factor VIII and/or Factor IX. Except as admitted or denied above, to the extent the matters set forth in Paragraph 45 are intended to constitute allegations of a defect, wrongdoing or a failure to exercise due care directed to Bayer and/or its predecessors, Bayer denies them. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 45 of the Complaint.

46. Beginning in about 1978, Defendants BAXTER, CUTTER and ALPHA began targeting homosexual donors in known urban gay communities. Because urban homosexuals had been reported in the 1970's to have exceptionally high prevalence of Hepatitis B infection, Defendants knew that such donors would provide a reliable source of plasma for the manufacture of commercially valuable HBIG.

PARAGRAPH NO. 46 ANSWER: The phrase "targeting" is not a plain statement to which Bayer can or is required to respond. To the extent the matters set forth in Paragraph 46 are intended to constitute allegations of a defect, wrongdoing or a failure to exercise due care directed at Bayer and/or its predecessors, Bayer denies them. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 46 of the Complaint.

47. It was also well-known in the public health community by the 1970's that urban homosexuals engaged in promiscuous sexual practices that rapidly transmitted other diseases, including NANB Hepatitis, which were transmitted by blood, could not be isolated nor identified, and were believed to have serious adverse consequences. Despite this knowledge, Defendants used the same plasma pool from urban homosexuals to manufacture both HBIG and Factor VIII and IX.

PARAGRAPH NO. 47 ANSWER: To the extent the matters set forth in Paragraph 47 are intended to constitute allegations of a defect, wrongdoing or a failure to exercise due care directed at Bayer and/or its predecessors, Bayer denies them. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 47 of the Complaint.

48. Defendants continued this dual use of high risk plasma even after federal reports warned of the rapid spread of fatal immunosuppressive disease among the same homosexual

population from which Defendants heavily recruited. Defendants knew or should have known by no later than the summer of 1981 that urban homosexual males were not "suitable donors" within the meaning of federal regulations and/or other applicable standards of care.

PARAGRAPH NO. 48 ANSWER: To the extent they are directed to Bayer and/or its predecessors, Bayer denies the allegations in Paragraph 48 of the Complaint. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 48 of the Complaint.

49. By the 1970s, it was also well-established that plasma from prison populations carried a high risk of hepatitis and other blood-borne diseases, primarily because of the concentration of intravenous (IV) drug users in prisons. Despite knowledge of this risk, Defendants actively recruited prisoners for plasma used to manufacture Factor VIII and IX, while concealing or failing to disclose the risk to Plaintiffs, Plaintiffs' Decedent, his physicians, or the FDA.

PARAGRAPH NO. 49 ANSWER: To the extent they are intended to constitute allegations of defect, wrongdoing or a failure to exercise due care directed at Bayer and/or its predecessors, Bayer denies the allegations in Paragraph 49 of the Complaint. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 49 of the Complaint.

50. In light of Defendants' special knowledge of the disease patterns among urban homosexuals and prisoners, and their recruitment of such donors for Factor VIII and IX manufacture, Defendants had duties to: (a) promptly investigate the first reports of opportunistic infections among urban homosexuals in 1981; (b) discontinue the practice of using such high risk donors; (c) disclose the risk to Plaintiffs, Plaintiffs' Decedent, his physicians, and the FDA, including the ongoing risk of continuing to use Factor VIII and IX previously manufactured with high risk plasma and still

marketed to patients; (d) implement procedures to kill blood-borne diseases in the products; and (e) recall existing products from distribution or further use. Instead, Defendants continued to conceal their recruitment of high risk donors and resist warnings and recalls, and failed to implement procedures to make their products safe.

PARAGRAPH NO. 50 ANSWER: To the extent they are directed to Bayer and/or its predecessors, Bayer denies the allegations in Paragraph 50 of the Complaint. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 50 of the Complaint

D. Answer to Allegations Regarding Hepatitis B Core (HBc) Testing

51. By no later than 1978, Defendants knew of the availability of a new test to determine whether an individual had a history of viral Hepatitis, which would have disqualified the donor from providing plasma for the manufacture of Factor VIII or IX. By testing a person's serum for the presence of the core to the Hepatitis B antibody, a history of viral Hepatitis could be verified. This was known as the "HBc test." Published, peer-reviewed literature shows that the HBc test was in use by researchers to determine that homosexual AIDS victims had a history of viral Hepatitis by no later than December 1981. (Gottlieb, et al., "Pneumocystis Carinii Pneumonia and Mucosal Candidiasis in Previously Healthy Homosexual Men," NEW ENGLAND JOURNAL OF MEDICINE 1981; 305:1425-1431).

PARAGRAPH NO. 51 ANSWER: Some or all of the allegations in Paragraph 51 of the Complaint purport to refer to or describe a NHLBI report. Such report is in writing and speaks for itself. To the extent any remaining allegations of Paragraph 51 are inconsistent with the NHLBI report, or are intended to constitute allegations of a defect, wrongdoing or a failure to exercise due care directed to Bayer and/or its predecessors, Bayer denies them.

52. Use of the HBc test would have eliminated approximately 75% of homosexual plasma donors and over 90% of promiscuous urban homosexuals. It would have eliminated almost 100% of intravenous drug users.

PARAGRAPH NO. 52 ANSWER: Bayer denies the allegations in Paragraph 52 of the Complaint.

53. Use of the HBc and ALT tests by Defendants by 1981 would have eliminated the vast majority of the transmitters of HIV and HCV from the blood and plasma pools of the nation, before the height of the AIDS and Hepatitis C epidemics. If Defendants had implemented this test in a timely manner, Plaintiffs' Decedent would never have been infected with HIV or HCV as a result of factor concentrate use.

PARAGRAPH NO. 53 ANSWER: Bayer denies the allegations in Paragraph 53 of the Complaint.

54. Plaintiffs' Decedent and thousands of other people with hemophilia in Israel and other countries became infected by the AIDS and Hepatitis C viruses through repeated exposures from blood products manufactured from large pools of plasma donors (5,000 to 40,000). If Defendants had used the HBc and ALT tests to decrease by 70% to 90% the number of HIV and HCV positive donors who went into a pool, the infectivity of the product would have decreased substantially. Consequently, the rate of infection of people with hemophilia would have slowed down enormously, and the medical and scientific community would have been given more time to react appropriately to the HIV and Hepatitis C epidemics.

PARAGRAPH NO. 54 ANSWER: Bayer admits that some hemophiliacs treated with Factor VIII and Factor IX were infected with HIV and Hepatitis C. To the extent the matters set forth in Paragraph 54 of the Complaint are intended to constitute allegations of a defect,

wrongdoing or a failure to exercise due care directed to Bayer and/or its predecessors, Bayer denies them. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 54 of the Complaint.

55. As noted below, federal regulations required plasma donors to be in good health, and donors with a "history of viral Hepatitis" were by definition unacceptable as blood or blood plasma donors. Persons with a history of viral hepatitis were excluded not only because of the risk of transmitting Hepatitis B, but because such a history indicated a lifestyle or previous behavior of the prospective donor which carried the risk of transmitting other viruses in addition to hepatitis. A reasonable and prudent plasma fractionator would not accept a HBc positive donor and expect to be in compliance with federal regulations as of 1978.

PARAGRAPH NO. 55 ANSWER: The allegations in Paragraph 55 of the Complaint purport to quote from or characterize unspecified "federal regulations." Any federal regulation is in writing and speaks for itself. To the extent that Plaintiffs' allegations regarding the content of the federal regulation are inconsistent with the actual language of the regulation, Bayer denies them. Bayer further states that Bayer at all times complied with all applicable statutes and regulations, acted within the then existing state of medical and scientific knowledge, and proceeded with due care. To the extent the allegations in Paragraph 55 are intended to constitute allegations of a defect, wrongdoing or a failure to exercise due care directed to Bayer and/or its predecessors, Bayer denies them. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 55 of the Complaint.

56. After public reports of the first hemophilia AIDS cases in July 1982, government officials urged Defendants to implement the HBc test as a "surrogate" or "marker" to eliminate plasma contaminated by the transmitter of AIDS or Hepatitis C. HBc testing was also strongly

suggested to Defendants by the CDC at a meeting of the United States Public Health Service ("PHS") on January 4, 1983. Despite this urging, Defendants continued to use contaminated plasma donations that would have been excluded by the HBc test and continued to conceal from Plaintiffs, Plaintiffs' Decedent, his physicians, and the FDA the dangerous practice of targeting donors at highest risk for the very diseases that disqualified their plasma. At a January 6, 1983 meeting of Defendants' trade association, the Pharmaceutical Manufacturer's Association, Defendants agreed not to implement the highly effective HBc donor screening, and instead opted to use ineffective donor questionnaires that did little to screen out donors at high risk for AIDS and Hepatitis C transmission.

PARAGRAPH NO. 56 ANSWER: Bayer is without knowledge or information sufficient to form a belief as to the truth of the allegations in the first sentence in Paragraph 56 of the Complaint. To the extent they are directed to Bayer and/or its predecessors, Bayer denies any remaining allegations in Paragraph 56 of the Complaint. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 56 of the Complaint.

57. As late as December 13, 1983, years after the HBc test was available, a memorandum from CUTTER's responsible head Stephen Ojala to various CUTTER executives, reporting back on a meeting held by all Defendants, shows that all Defendants conspired to propose a "task force" to further study the use of HBc as an intentional, bad faith "delaying tactic for the implementation" of the test.

PARAGRAPH NO. 57 ANSWER: The allegations in Paragraph 57 of the Complaint purport to refer to, or describe a document. That document is in writing. To the extent allegations in Paragraph 57 are inconsistent with the document, Bayer denies them. Bayer admits

that in December 1983, certain representatives of the plasma industry, BPAC and the FDA were present at a meeting where the creation of a Task Force to evaluate and study the utility of HBc testing was proposed. Bayer denies that it conspired with anyone and denies that the proposed evaluation was proposed in bad faith or was intended to be an improper delaying tactic. To the extent the allegations in Paragraph 57 are intended to constitute allegations of a defect, wrongdoing or a failure to exercise due care directed to Bayer and/or its predecessors, Bayer denies those allegations. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 57 of the Complaint.

E. Answer to Allegations Regarding Heat Treatment and Solvent Detergent

58. In the late 1970s and early 1980s, it was recognized that viruses were in all AHF products, including Factor VIII and IX. Heat treatment and solvent detergent was available at that time to eliminate many of these viruses, including HIV and HCV. Defendants were required to take reasonable steps to eliminate contamination, but Defendants failed to utilize these available technologies to eliminate the viruses in a timely manner.

PARAGRAPH NO. 58 ANSWER: Bayer admits that in the late 1970's to early 1980's, hepatitis was a known, accepted and warned of risk associated with the use of Factor VIII and Factor IX. Bayer admits that some "[t]reatment with solvents and/or detergents" kill HCV. Bayer denies that such a treatment was "available" in "the late 1970's" and denies that all solvent detergent treatments kill HCV. To the extent the matters set forth in Paragraph 58 of the Complaint are intended to constitute allegations of a defect, wrongdoing or a failure to exercise due care directed to Bayer and/or its predecessors, Bayer denies them. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 58 of the Complaint.

59. The 1977 NHLBI Report noted that albumin, another plasma product, was "heat treated to remove almost all danger of hepatitis." (Id., at p. 49). Defendant ARMOUR'S memorandum of June 1983 acknowledged that no cases of AIDS had been reported in heat-¬treated albumin users, but misleadingly states that heat treatment of Factor VIII and IX was not yet feasible. It was clearly known by no later than 1977 that heat treatment was an effective way to make blood products safer, but Defendants wrongfully refused to implement such procedures as to Factor VIII and IX. In 1995, the National Institutes of Health Institute of Medicine ("IOM") issued a report on the hemophilia AIDS epidemic which concluded that defendants "did not seriously consider alternative inactivation processes," including heat treatment, and that "heat treatment processes to prevent the transmission of hepatitis could have been developed before 1980." Heat treated, HIV-safe factor concentrates were not introduced by any Defendant until 1983, and were not universally in use until 1985.

PARAGRAPH NO. 59 ANSWER: The allegations in Paragraph 59 of the Complaint purport to refer to, or describe a documents. Those documents are is in writing. To the extent allegations in Paragraph 59 are inconsistent with these documents, Bayer denies them. To the extent the allegations in Paragraph 59 are intended to constitute allegations of a defect, wrongdoing or a failure to exercise due care directed to Bayer and/or its predecessors, Bayer denies those allegations. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 59 of the Complaint.

60. In addition to heat treatment, solvent detergent treatment was available to Defendants by the late 1970's as a simple and effective method of eliminating viruses in their factor concentrate products. Solvent detergent effectively kills viruses such as HIV and HCV by destroying the viruses' lipid envelope. It is simpler than heat treatment, and unlike heat treatment does not interfere with the

Factor VIII and IX proteins needed for blood clotting.

PARAGRAPH NO. 60 ANSWER: Bayer admits that some treatments involving solvent and/or detergent kill HIV and HCV by action on the lipid envelope. Bayer denies that such treatments are simple and denies that a solvent detergent treatment was "available" in "the late 1970's" and denies that all solvent detergent treatments kill HIV and HCV. To the extent the matters set forth in Paragraph 60 of the Complaint are intended to constitute allegations of a defect, wrongdoing or a failure to exercise due care directed to Bayer and/or its predecessors, Bayer denies them. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 60 of the Complaint.

61. Solvent detergents were well-known, commercially available products as of the 1970's, and studies in which solvent detergent treatment was used to disrupt viruses were published in the 1970's in peer-reviewed journals. In 1980, Dr. Edward Shanbrom, a former BAXTER scientist, received a patent for a solvent detergent treatment process for viral inactivation of factor concentrate. Dr. Shanbrom describes the implementation of this process as "as easy as washing your hands."

PARAGRAPH NO. 61 ANSWER: The allegations in the first sentence of Paragraph 61 of the Complaint refer to or describe certain unidentified studies involving solvent detergents and viruses. To the extent such studies exist, they are in writing and speak for themselves. To the extent that Plaintiffs' allegations regarding the content of those studies are inconsistent with the actual language of the studies, or are intended to constitute allegations of a defect, wrongdoing or a failure to exercise due care directed to Bayer and/or its predecessors, Bayer denies them. Bayer admits that Dr. Shanbrom is a former Baxter scientist. To the extent the matters set forth in the second and third sentences of Paragraph 61 are intended to constitute

allegations of a defect, wrongdoing, or a failure to exercise due care directed to Bayer and/or its predecessors, Bayer denies them. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 61 of the Complaint.

62. After receiving the patent, Dr. Shanbrom approached various Defendants about implementing the solvent detergent method, but these Defendants wrongfully refused to implement the method. Several of the Defendants refused to even commit any resources to investigate the method. However, in June, 1985, the New York Blood Center ("NYBC") obtained a license from the FDA to implement the process for Factor VIII. The NYBC obtained a license to use the process in 1987. On information and belief, by 1987, all Defendants except ARMOUR were using the process to virally inactivate their Factor VIII blood products.

PARAGRAPH NO. 62 ANSWER: Bayer admits that NYBC obtained a license from the FDA to market a solvent detergent inactivated factor concentrate in 1985. Bayer denies that it wrongfully refused to implement the solvent detergent "method." Except as admitted or denied above, to the extent the matters set forth in Paragraph 62 are intended to constitute allegations of a defect, wrongdoing or a failure to exercise due care directed at Bayer and/or its predecessors, Bayer denies them. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 62 of the Complaint.

63. Although heat treatment was effective in destroying the HIV virus, it was ineffective in destroying HCV and HBV. A recent CDC study reported that "84% of previously untreated patients infused with dry-heated Factor VIII products developed non-A, non B hepatitis ... several case reports of probable transmission of HBV and HCV through vapor heat-treated and pasteurized products later appeared." (Risk Factor for Infection with HBV and HCV in a Large Cohort of Hemophiliac Males: Soucie, Richardson, Evatt et al; Transfusion, 2001; 41:338-343)

PARAGRAPH NO. 63 ANSWER: Bayer admits that some forms of heat treatment were effective in destroying one or more of the following: HIV, HCV & HBV. The allegations in Paragraph 63 of the Complaint purport to refer to or describe a CDC study. Such study is in writing and speaks for itself. To the extent the allegations in Paragraph 63 are inconsistent with the CDC study, or are intended to constitute allegations of a defect, wrongdoing or a failure to exercise due care directed to Bayer and/or its predecessors, Bayer denies them.

64. The same CDC study reported that "solvent detergent treatment of blood components found to be more effective against enveloped viruses than heat treatment ... No cases of HBV, HCV, or HIV transmission through solvent detergent virus inactivated products have been found in prospective studies of previously untreated patients..."

PARAGRAPH NO. 64 ANSWER: The allegations in Paragraph 64 of the Complaint purport to refer to or describe a CDC study. Such study is in writing and speaks for itself. To the extent the allegations in Paragraph 64 are inconsistent with the CDC study, or are intended to constitute allegations of a defect, wrongdoing or a failure to exercise due care directed to Bayer and/or its predecessors, Bayer denies them.

65. The study further reported "in our data, the first dramatic decline in HCV prevalence appears in the 1987 birth cohort. The drop in HCV transmission correlates with the licensing of solvent detergent treatment of factor IX products in 1987. In addition, this cohort would have been the first to benefit from the screening of blood donors using the surrogate markers ALT (begun in late 1986) and anti-HBc (begun in 1987), testing that was associated with a markedly decreased risk of HCV infection from blood transfusions."

PARAGRAPH NO. 65 ANSWER: The allegations in Paragraph 65 of the Complaint purport to refer to or describe a CDC study. Such study is in writing and speaks for itself. To

the extent the allegations in Paragraph 65 are inconsistent with the CDC study, or are intended to constitute allegations of a defect, wrongdoing or a failure to exercise due care directed to Bayer and/or its predecessors, Bayer denies them.

66. The study states further that "the residual transmissions after 1987 possibly represent the use of product already manufactured or product manufactured during the interval required to implement the new technology. The 18-month shelf life of factor concentrates placed those people with hemophilia born as late as 1989 at risk of infection." The study goes on to recommend testing for all people with hemophilia who received infusions of the defendant's blood products prior to 1992.

PARAGRAPH NO. 66 ANSWER: The allegations in Paragraph 66 of the Complaint purport to refer to or describe a CDC study. Such study is in writing and speaks for itself. To the extent the allegations in Paragraph 66 are inconsistent with the CDC study, or are intended to constitute allegations of a defect, wrongdoing or a failure to exercise due care directed to Bayer and/or its predecessors, Bayer denies those allegations.

67. The failure of Defendants to implement solvent detergent viral inactivation techniques in a timely manner, to warn of the risk that heat treated Factor VIII and IX blood products could transmit HBV and HCV, and to recall heat treated products that posed this risk caused the needless infection of thousands of people with hemophilia with HCV and HBV after 1983, including Plaintiffs' Decedent. Even after Defendants knew or should have known that the solvent detergent process effectively destroyed HCV and HBV, as well as HIV, they continued to sell heat treated Factor VIII and IX, and refused to recall these dangerous products from the market.

PARAGRAPH NO. 67 ANSWER: Bayer denies the allegations in Paragraph 67 of the Complaint.

F. Answer to Allegations Regarding Non-Heat Treated Factor Concentrates

68. Between 1983 and 1985, Defendants stopped selling non-heat treated factor concentrate in the United States and introduced a vastly safer heat-treated version. However, one or more Defendants, including BAXTER (successor to IMMUNO) and BAYER (successor to CUTTER) continued to allow their remaining stocks of non-heat treated product to remain on the market in Israel and other countries after ceasing sales of such product in the United States, despite knowledge that the non-heat treated product was contaminated with HIV and/or HCV.

PARAGRAPH NO. 68 ANSWER: In response to the allegations in the first sentence in Paragraph 68 of the Complaint, Bayer admits that Bayer or one of its predecessors stopped distributing certain non heat-treated Factor VIII in the United States in 1984, and that Bayer or its predecessors introduced certain new heat-treated factor concentrates in 1984. To the extent the matters set forth in Paragraph 68 are intended to constitute allegations of a defect, wrongdoing or a failure to exercise due care directed at Bayer and/or its predecessors, Bayer denies them. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 68 of the Complaint.

69. As detailed in this Complaint, by the end of 1982 Defendants' internal communications in the United States revealed their awareness of the AIDS risk posed by their products, but they continued to disavow the connection between AIDS and factor concentrates in their communications to foreign doctors and persons with hemophilia. In mid-1983, months after CUTTER executives authored internal memos expressing their belief that factor concentrates transmitted AIDS, the company wrote a letter to its foreign distributors, in which it characterized the concern over AIDS as an "irrational response," and dismissed the notion that AIDS could be transmitted by factor concentrates as "unsubstantiated speculation." (Internal Defendant documents)

CUTTER told the distributors that "[w]hat little evidence exists . . . tends to suggest that AHF concentrates have no direct role in [the AIDS] syndrome."

PARAGRAPH NO. 69 ANSWER: The allegations in Paragraph 69 of the Complaint purport to refer to, or describe Defendants' internal communications. Such communications are in writing. To the extent allegations in Paragraph 69 are inconsistent with Defendants' internal communications, or are intended to constitute allegations of a defect, wrongdoing or a failure to exercise due care directed to Bayer and/or its predecessors, Bayer denies them. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 69 of the Complaint.

70. Even after Defendants introduced heat-treated products that did not transmit HIV and touted the safety of these new products, they continued selling their contaminated non-HT product abroad.

PARAGRAPH NO. 70 ANSWER: To the extent the matters set forth in Paragraph 70 are intended to constitute allegations of a defect, wrongdoing or a failure to exercise due care directed at Bayer and/or its predecessors, Bayer denies them. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 70 of the Complaint.

71. In October of 1984, the CDC issued a report announcing that 74% recipients of Factor VIII concentrates made from plasma derived from American donors were HIV positive. CDC data supports the role American factor played in spreading AIDS among Plaintiffs' Decedent and other persons with hemophilia in Israel. The CDC report also publicized studies showing that heat treatment effectively killed the HIV virus. Upon information and belief, Defendants did not upon receiving this news recall or withdraw their unheated products from Israel. Such products therefore

remained on the shelves and continued infecting Israeli hemophiliacs until their expiration dates.

PARAGRAPH NO. 71 ANSWER: The allegations in Paragraph 71 of the Complaint purport to refer to, or describe a CDC report. Such report is in writing and speaks for itself. To the extent the allegations in Paragraph 71 are inconsistent with the CDC report, or are intended to constitute allegations of a defect, wrongdoing or a failure to exercise due care directed to Bayer and/or its predecessors, Bayer denies them. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in the first sentence of Paragraph 71 of the Complaint.

G. Answer to Allegations Regarding Misrepresentation and Fraudulent Concealment

72. Defendants engaged in a pattern and practice of fraudulent concealment of their dangerous practices, fraudulent misrepresentations of the extent of their efforts to assure safety, and fraudulent misrepresentations that understated the risk of AIDS and Hepatitis C, in order to maintain profits from both factor concentrates and HBIG. A summary of Defendants' fraudulent misrepresentations and concealment is set forth below.

PARAGRAPH NO. 72 ANSWER: Bayer denies the allegations in Paragraph 72 of the Complaint.

73. On July 27, 1982, a meeting of the Public Health Service was held as the result of the CDC's report of three people with hemophilia who contracted AIDS. The responsible heads of ARMOUR, ALPHA, CUTTER and BAXTER HEALTHCARE were in attendance, along with officials from the National Hemophilia Foundation, CDC and FDA. At least three of the Defendants were aware that they had used cryoprecipitate containing plasma from known, targeted homosexuals in the manufacture of Factor VIII and IX blood products. These products had a shelf life of two and three years, respectively, and were either in production or already on the shelves in pharmacies

waiting to be infused by people with hemophilia who purchased them. The Defendants involved, BAYER, BAXTER and ALPHA, failed to disclose these facts at the meeting where CDC officials Dr. Don Francis and Dr. Jeff Koplin were present, despite knowledge that the CDC's primary concern at that meeting was the infection of Factor VIII and IX by the transmitter of AIDS, which was already well-known to be epidemic in the targeted homosexual population. (CUTTER memorandum dated August 3, 1982)

PARAGRAPH NO. 73 ANSWER: Bayer admits that on July 27, 1982, a meeting was held and the "responsible head" of Cutter was in attendance, along with officials from the National Hemophilia Foundation (hereinafter referred to as "NHF"), the CDC, the FDA and numerous others. The allegations in Paragraph 73 of the Complaint purport to refer to, or describe Defendants' internal communications. Such communications are in writing. To the extent allegations in Paragraph 73 are inconsistent with Defendants' internal communications, Bayer denies them. Except as admitted or denied above, to the extent the matters set forth in Paragraph 73 are intended to constitute allegations of a defect, wrongdoing or a failure to exercise due care directed at Bayer and/or its predecessors, Bayer denies them. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 73 of the Complaint.

74. In or about December, 1982, Rodell, the responsible head for BAXTER HEALTHCARE, entered into an agreement with officials of the FDA to the effect that BAXTER HEALTHCARE would no longer use prison plasma in the production of factor concentrates. In fact, BAXTER HEALTHCARE, unbeknownst to the FDA, continued to use prison plasma in factor concentrate production through October 1983. (BAXTER HEALTHCARE memorandum dated October 20, 1983.)

PARAGRAPH NO. 74 ANSWER: Bayer is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 74 of the Complaint.

75. On January 5, 1983, an AIDS meeting was held at Children's Orthopedic Hospital in Los Angeles, California, the largest hemophilia treatment center in the United States. Representatives of four Defendants were present at the meeting with treaters and patients. The purpose of the meeting was to have Defendants' representatives answer patients' questions about AIDS transmission through factor concentrates. A patient asked representatives from CUTTER, ALPHA, ARMOUR and BAXTER the following question: "Is the plasma from homosexuals, prisoners, Haitians or other high risk persons being used in the manufacture of concentrates?" No Defendants admitted targeting or using plasma from homosexuals, prisoners or inner city IV drug abusers. Dr. Goodman from BAXTER HEALTHCARE answered regarding BAXTER HEALTHCARE'S use of known homosexuals as follows: "We are changing the nature of questions to homosexuals to the best of our ability." CUTTER'S responsible head, Stephen Ojala, an ALPHA representative, and ARMOUR'S Karl Hansen made no response to the question. This partial and misleading response amounted to concealment of the true risk created by the use of known homosexuals, IV drug abusers and prisoners in the manufacture of factor concentrates.

PARAGRAPH NO. 75 ANSWER: Bayer admits that on January 5, 1983 a meeting was held at Children's Orthopedic Hospital in Los Angeles, California. Bayer admits that a Cutter representative was in attendance at that meeting. Bayer denies that any Cutter representative made any "misleading statements." Except as admitted above, to the extent the matters set forth in Paragraph 75 are intended to constitute allegations of a defect, wrongdoing or a failure to exercise due care directed at Bayer and/or its predecessors, Bayer denies them.

Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 75 of the Complaint.

76. At the January 5, 1983 meeting, and in the presence of the patients, one of the treating physicians, Dr. Kasper, asked CUTTER'S Stephen Ojala: "These [plasma] centers seem to be in rundown centers of town. Is there a move to move them to rural towns?" Ojala answered: "Many of the centers are in smaller communities and in towns such as Ypsilanti, Seattle, Clayton, NC., and San Diego. We do not have centers in L.A. or San Francisco." This answer was misleading because Ojala failed to state that CUTTER'S largest and first plasma center was located at Arizona State Penitentiary. CUTTER also had a center at the Las Vegas Prison. Ojala and CUTTER were well aware of the CDC's and FDA's concern over use of prison plasma, due to homosexual practices and drug abuse in the prison donor population. Many of CUTTER'S centers were in inner city areas frequented by IV drug abusers, such as downtown Oakland, California. CUTTER had also used plasma from centers which targeted known homosexuals. In August 1982, CUTTER quarantined plasma from the Valley Medical Center, a center which targeted known homosexuals, because a donor was hospitalized with full blown AIDS. The plasma was intended for Factor IX and HBIG production, but was not used because it had thawed on the way to the processing plant. Upon receiving a report of this incident from CUTTER, the FDA indicated a recall might have been necessary if the plasma had been incorporated into factor concentrate final product. Ojala omitted any mention of these facts and circumstances in his response to Dr. Kasper regarding the location of their plasma centers. (CUTTER memorandum dated January 5,1983.)

PARAGRAPH NO. 76 ANSWER: Bayer admits that it obtained plasma from collection centers in Arizona, Las Vegas, Nevada and Oakland, California. Bayer denies that any Cutter representative made any misleading statements. The allegations in Paragraph 76 of

the Complaint purport to refer to, or describe Defendants' internal communications. Such communications are in writing. To the extent allegations in Paragraph 76 are inconsistent with Defendants' internal communications, Bayer denies them. Except as admitted or denied above, to the extent the matters set forth in Paragraph 76 are intended to constitute allegations of a defect, wrongdoing or a failure to exercise due care directed at Bayer and/or its predecessors, Bayer denies them. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 76 of the Complaint.

77. On January 14, 1983, Dr. Michael Rodell and the other responsible heads from Defendants attended a meeting of the National Hemophilia Foundation ("NHF"). The purpose of the meeting was to have Defendants explain to the NHF what steps they were prepared to take to safeguard the plasma supply from potential AIDS transmitters. Defendants were very concerned that the NHF would insist on a recommendation that HBc testing be implemented, consistent with the CDC recommendation 10 days earlier. BAXTER HEALTHCARE, under Rodell's supervision, had already conducted a survey of several of their donor centers to determine how many donors they would lose if the test were implemented. BAXTER HEALTHCARE had decided that up to 16% of their donors would not pass the test. Further, BAXTER HEALTHCARE'S high titered immunoglobulin donors would be eliminated. In order to defer an NHF recommendation that HBc testing be used, Rodell told NHF officials that surrogate testing was in the "R and D," or "Research and Development," stage currently. Rodell concealed the fact that the CDC had strongly recommended use of the HBc Antibody test as a screening device for donors at high risk for AIDS transmission. The HBc Antibody test was not in the "R and D" stage, and was suitable for use as a screening device for high risk AIDS and Hepatitis C donors. In fact, the HBc test had been approved in 1979 by the FDA as a diagnostic test to be used to ascertain a history of previous hepatitis B

infection, and as a screening device for blood and plasma donors. The test had the capability of identifying all donors with a history of viral hepatitis. Donors with a hepatitis history were specifically prohibited pursuant to the federal regulations (21 C.F.R. § 640.63). Rodell acknowledged that implementation of the HBc test would eliminate high titered immunoglobulin donors, but failed to disclose that opposition to use of the test was based on economic rather than safety concerns.

PARAGRAPH NO. 77 ANSWER: Bayer admits that a representative attended a meeting on January 14, 1983 with the NHF. To the extent the matters set forth in Paragraph 77 are intended to constitute allegations of a defect, wrongdoing or a failure to exercise due care directed at Bayer and/or its predecessors, Bayer denies them. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 77 of the Complaint.

78. At the January 14, 1983 meeting, ALPHA, CUTTER and BAXTER concealed their advertising in publications distributed among urban homosexuals, for the specific purpose of attracting them to plasma centers which supplied high titered plasma to the Defendants. CUTTER and ALPHA concealed their extensive use of prison plasma, and BAXTER discussed plans to phase out prison plasma during the coming year. However, none of the Defendants revealed their "gentlemen's agreement" with the FDA to discontinue use of these plasma sources immediately. (CUTTER Memorandum dated January 17, 1983.)

PARAGRAPH NO. 78 ANSWER: Some or all of the allegations in Paragraph 78 of the Complaint purport to refer to, describe or be based on a "Cutter Memorandum". Such a document is in writing. To the extent the allegations in Paragraph 78 are inconsistent with that document, or are intended to constitute allegations of a defect, wrongdoing or a failure to exercise due care directed at Bayer and/or its predecessors, Bayer denies them. Bayer is without

knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 78 of the Complaint.

79. On or about December 15, 1983, Rodell, then the head of ARMOUR, told members of the federal Blood Product Advisory Committee (BPAC) and FDA officials that the Defendants wanted a three month deferral in implementation of any recommendations by the BPAC or FDA that HBc testing be required for plasma donors. Rodell told the FDA that the purpose of the deferral was to prepare a response to the proposed recommendation. In fact, the Defendants had agreed to seek the three month hiatus as a "delaying tactic" against implementing the test, and the request for a deferral was made in bad faith. (CUTTER memorandum dated December 13, 1983.)

PARAGRAPH NO. 79 ANSWER: Bayer admits that, at a meeting on or about December 15, 1983, Michael Rodell proposed to members of the Blood Products Advisory Committee and FDA officials the creation of a Task Force to evaluate HBc testing and requested an additional three months to provide more information about its use. Bayer denies that this was in any way intended to create an improper delaying tactic or was done in bad faith. The allegations in the final sentence in Paragraph 79 of the Complaint purport to refer to, describe or be based on a "Cutter Memorandum". Such a document is in writing. To the extent the allegations in the final sentence of Paragraph 79 are inconsistent with the document, or are intended to constitute allegations of a defect, wrongdoing or a failure to exercise due care directed at Bayer and/or its predecessors, Bayer denies those allegations. To the extent the matters set forth in Paragraph 79 are intended to constitute allegations of a defect, wrongdoing or a failure to exercise due care directed at Bayer and/or its predecessors, Bayer denies them. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 79 of the Complaint.

80. It was strongly suggested by the CDC on July 27, 1982, that AIDS had a viral etiology similar to Hepatitis B because of the risk groups involved. These risk groups comprised a substantial portion of CUTTER'S plasma donor sources. CUTTER took no meaningful action to screen out donors at the highest risk for AIDS and Hepatitis C transmission at any time during the epidemic. In fact, they continued to market products containing plasma from these groups throughout 1982, 1983 and 1984 worldwide. Even more egregiously, CUTTER and other Defendants continued to market high risk non-heat treated factor concentrate abroad after ceasing sales of such product in the United States in favor of vastly safer heat treated product.

PARAGRAPH NO. 80 ANSWER: Bayer denies that it used donors at a high risk for Hepatitis B or Hepatitis C. Bayer at all times complied with all applicable statutes and regulations, acted within the then existing state of medical and scientific knowledge, and proceeded with due care. Except as admitted or denied above, to the extent the matters set forth in Paragraph 80 are intended to constitute allegations of a defect, wrongdoing or a failure to exercise due care directed at Bayer and/or its predecessors, Bayer denies them. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 80 of the Complaint.

80. Defendants, jointly and individually, fraudulently misrepresented the risk of AIDS and Hepatitis C due to factor concentrates, failed to disclose accurate warnings of the risk to Plaintiffs, Plaintiffs' Decedent or his physicians, and fraudulently purported to be doing "everything possible" to improve safety, when in fact Defendants maximized the risk by recruiting high risk donors and by resisting and obstructing HBc testing, heat treatment, and other measures that would truly have reduced the risk.

PARAGRAPH NO. 80 ANSWER: Bayer denies the allegations in Paragraph 80 of the Complaint.

H. Answer to Allegations Regarding Federal Regulations

81. Blood derivatives such as Factor VIII and IX are prescription biologicals subject to federal regulation as both "biological products" and "drugs." Public Health Service Act, "Regulation of Biological Products," 42 U.S.C. § 262; Food, Drug & Cosmetic Act ("FDCA"), 21 U.S.C. § 301, et seq.

> (a) 21 U.S.C. § 331(b) prohibited "adulteration or misbranding of any … drug, ..."
>
> (b) 21 U.S.C. § 351(a)(2)(B) provided that "[a] drug . . . shall be deemed to be adulterated . . . if . . . the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this chapter as to safety. . . ."
>
> (c) 21 U.S.C. § 352 provided that "[a] drug... shall be deemed to be misbranded. .. if its labeling is false or misleading in any particular."
>
> (d) 21 U.S.C. § 352(f)(2) provided that a drug shall be deemed to be "misbranded" unless its labeling bears "adequate warnings against use. .. where its use may be dangerous to health."
>
> (e) 21 U.S.C. § 352(n) provided that a drug shall be deemed to be "misbranded" unless the labeling included information concerning side effects and contraindications as required in federal regulations.
>
> (f) 21 U.S.C. § 321(n) provided that if an article is alleged to be misbranded because the labeling or advertising is misleading, then the determination of whether the labeling or advertising is misleading shall take into account "not only representations made or suggested" by affirmative statements, "but also the extent to which the labeling or advertising fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use" of the drug.

PARAGRAPH NO. 81 ANSWER: The allegations in Paragraph 81 of the Complaint purport to quote from sections of the United States Code. The United States Code is in writing and speaks for itself. To the extent that Plaintiffs' allegations regarding the content of the

United States Code are inconsistent with the actual language of the United States Code, Bayer denies those allegations. Bayer further states that Bayer at all times complied with all applicable statutes and regulations, acted within the then existing state of medical and scientific knowledge, and proceeded with due care. To the extent the allegations in Paragraph 81 are intended to constitute allegations of a defect, wrongdoing or a failure to exercise due care directed to Bayer and/or its predecessors, Bayer denies them. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 81 of the Complaint.

82. At all times material to this Complaint, 21 C.F.R. § 201.57(e) provided as follows, with respect to information to be provided with the sale of Defendants' products:

> Warnings: Under this section heading, the labeling shall describe serious adverse reactions and potential safety hazards, limitations in use imposed by them, and steps that should be taken if they occur. The labeling shall be revised to include a warning as soon as there is reasonable evidence of an association with a drug; a causal relationship need not have been proved.

PARAGRAPH NO. 82 ANSWER: The allegations in Paragraph 82 of the Complaint purport to quote from sections of the Code of Federal Regulations. The Code of Federal Regulations is in writing and speaks for itself. To the extent that Plaintiffs' allegations regarding the content of the Code of Federal Regulations are inconsistent with the actual language of the Code of Federal Regulations, Bayer denies those allegations. Bayer further states that Bayer at all times complied with all applicable statutes and regulations, acted within the then existing state of medical and scientific knowledge, and proceeded with due care. To the extent the allegations in Paragraph 82 are intended to constitute allegations of a defect, wrongdoing or a failure to exercise due care directed to Bayer and/or its predecessors, Bayer

denies them. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 82 of the Complaint.

83. At all times material to this Complaint, 21 C.F.R. § 200.5 provided as follows:

> Manufacturers and distributors of drugs and the Food and Drug Administration occasionally are required to mail important information about drugs to physicians and others responsible for patient care. In the public interest, such mail shall be distinctive in appearance so that it will be promptly recognized and read.

PARAGRAPH NO. 83 ANSWER: The allegations in Paragraph 83 of the Complaint purport to refer to or describe sections of the Code of Federal Regulations. The Code of Federal Regulations is in writing and speaks for itself. To the extent that Plaintiffs' allegations regarding the content of the Code of Federal Regulations are inconsistent with the actual language of the Code of Federal Regulations, Bayer denies those allegations. Bayer further states that Bayer at all times complied with all applicable statutes and regulations, acted within the then existing state of medical and scientific knowledge, and proceeded with due care. To the extent the allegations in Paragraph 83 are intended to constitute allegations of a defect, wrongdoing or a failure to exercise due care directed to Bayer and/or its predecessors, Bayer denies them. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 83 of the Complaint.

84. At all times material to this Complaint, Part 606 of 21 C.F.R. set forth "Current Good Manufacturing Practices" for biological products generally, and 21 C.F.R. § 640, et seq., set forth additional good manufacturing practices for blood and plasma biologicals.

PARAGRAPH NO. 84 ANSWER: The allegations in Paragraph 84 of the Complaint purport to quote from sections of the Code of Federal Regulations. The Code of Federal Regulations is in writing and speaks for itself. To the extent that Plaintiffs' allegations

regarding the content of the Code of Federal Regulations are inconsistent with the actual language of the Code of Federal Regulations, Bayer denies those allegations. Bayer further states that Bayer at all times complied with all applicable statutes and regulations, acted within the then existing state of medical and scientific knowledge, and proceeded with due care. To the extent the allegations in Paragraph 84 are intended to constitute allegations of a defect, wrongdoing or a failure to exercise due care directed to Bayer and/or its predecessors, Bayer denies them. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 84 of the Complaint.

85. At all times material to this Complaint, 21 C.F.R. § 606.140(a) provided:

> Laboratory control procedures shall include: The establishment of scientifically sound and appropriate specifications, standards and test procedures to assure that blood and blood components are safe, pure, potent and effective.

PARAGRAPH NO. 85 ANSWER: The allegations in Paragraph 85 of the Complaint purport to quote from sections of the Code of Federal Regulations. The Code of Federal Regulations is in writing and speaks for itself. To the extent that Plaintiffs' allegations regarding the content of the Code of Federal Regulations are inconsistent with the actual language of the Code of Federal Regulations, Bayer denies those allegations. Bayer further states that Bayer at all times complied with all applicable statutes and regulations, acted within the then existing state of medical and scientific knowledge, and proceeded with due care. To the extent the allegations in Paragraph 85 are intended to constitute allegations of a defect, wrongdoing or a failure to exercise due care directed to Bayer and/or its predecessors, Bayer denies them. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 85 of the Complaint.

86. At all times material to this Complaint, 21 C.F.R. § 640.60 defined "Source Plasma (1-luman)" as

> the fluid portion of human blood which has been stabilized against clotting, collected by plasmapheresis, and is intended as source material for further manufacture into blood derivatives (a portion of pooled plasma separable by chemical means) intended for injection.

PARAGRAPH NO. 86 ANSWER: The allegations in Paragraph 86 of the Complaint purport to quote from sections of the Code of Federal Regulations. The Code of Federal Regulations is in writing and speaks for itself. To the extent that Plaintiffs' allegations regarding the content of the Code of Federal Regulations are inconsistent with the actual language of the Code of Federal Regulations, Bayer denies those allegations. Bayer further states that Bayer at all times complied with all applicable statutes and regulations, acted within the then existing state of medical and scientific knowledge, and proceeded with due care. To the extent the allegations in Paragraph 86 are intended to constitute allegations of a defect, wrongdoing or a failure to exercise due care directed to Bayer and/or its predecessors, Bayer denies them. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 86 of the Complaint.

87. At all times material to this Complaint, 21 C.F.R. § 640.63(c), entitled "Qualification of Donor," provided as follows with respect to donors of source plasma:

> Donors shall be in good health on the day of donation, as indicated in part by: . . . (9) freedom from any disease, other than malaria, transmissible by blood transfusion, in so far as can he determined by history and examination indicated in this section; (10) freedom of the arms and forearms from skin punctures or scars indicative of addiction to self-injected narcotics; (11) freedom from a history of viral hepatitis; (12) freedom from a history of close contact within six months of donation with an individual having viral hepatitis; . . . .

Further, 21 C.F.R. § 640.63(a) provided that the method of determining "suitability of a donor" included "tests" as well as the taking of a history and physical examination.

PARAGRAPH NO. 87 ANSWER: The allegations in Paragraph 87 of the Complaint purport to quote from sections of the Code of Federal Regulations. The Code of Federal Regulations is in writing and speaks for itself. To the extent that Plaintiffs' allegations regarding the content of the Code of Federal Regulations are inconsistent with the actual language of the Code of Federal Regulations, Bayer denies those allegations. Bayer further states that Bayer at all times complied with all applicable statutes and regulations, acted within the then existing state of medical and scientific knowledge, and proceeded with due care. To the extent the allegations in Paragraph 87 are intended to constitute allegations of a defect, wrongdoing or a failure to exercise due care directed to Bayer and/or its predecessors, Bayer denies them. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 87 of the Complaint.

88. At all times material to this Complaint, 21 C.F.R. § 606.140 provided as follows:

> Laboratory control procedures shall include: (a) The establishment of scientifically sound and appropriate specifications, standards and test procedures to ensure that blood and blood components are safe, pure, potent and effective.

PARAGRAPH NO. 88 ANSWER: The allegations in Paragraph 88 of the Complaint purport to quote from sections of the Code of Federal Regulations. The Code of Federal Regulations is in writing and speaks for itself. To the extent that Plaintiffs' allegations regarding the content of the Code of Federal Regulations are inconsistent with the actual language of the Code of Federal Regulations, Bayer denies those allegations. Bayer further states that Bayer at all times complied with all applicable statutes and regulations, acted within the then existing state of medical and scientific knowledge, and proceeded with due care. To the extent the allegations in Paragraph 88 are intended to constitute allegations of a defect, wrongdoing or a failure to exercise due care directed to Bayer and/or its predecessors, Bayer

denies them. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 88 of the Complaint.

89. The foregoing statutes and regulations are evidence of the standard of care Defendants should have employed in the manufacture and sale of Factor VIII and Factor IX. Defendants violated the foregoing regulations and/or failed to comply with applicable standards of care by: (a) marketing "adulterated" products that were unsafe as a result of failure to comply with "Current Good Manufacturing Practice"; (b) marketing "misbranded" products that were misleading and failed to disclose or warn of health dangers; (c) failing to warn of serious adverse reactions and potential safety hazards as soon as there was reasonable evidence of an association with the product; (d) failing to exclude intravenous drug users who were unsuitable donors; (e) failing to exclude donors with a history of viral Hepatitis who were unsuitable donors; (f) affirmatively seeking out unsuitable donors known to have viral Hepatitis antibodies, as well as prison populations known to include substantial numbers of intravenous drug users, for inclusion of their plasma in the pools used to make Factor VIII and Factor IX; (g) failing to disclose their use of dangerous donors; and (h) failing to use appropriate tests and/or procedures to assure the products were safe.

PARAGRAPH NO. 89 ANSWER: The allegations in Paragraph 89 including subparagraphs (a) through (h), of the Complaint state conclusions of law to which no response is required. To the extent that a response is required and to the extent they are directed to Bayer and/or its predecessors, Bayer denies the allegations in Paragraph 89 of the Complaint. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 89 of the Complaint.

I. Answer to Allegations Regarding Conspiracy, Concert of Action and Group Liability

90. Defendants, and each of them, acted in concert and participated in a conscious and deliberate conspiracy to act negligently, fraudulently and with willful and wanton disregard for the rights and safety of blood product users, in connection with the manufacture of Factor VIII and IX blood products and the collection of constituent plasma.

PARAGRAPH NO. 90 ANSWER: Bayer denies the allegations in Paragraph 90 of the Complaint.

91. Defendants herein tacitly and explicitly agreed to avoid upgrading industry standards. For example, the technology to virally inactivate factor concentrates existed in the early 1970s, but was not seriously investigated by any of the Defendants until the early 1980s, despite its effective use in Europe. Use of the HBc antibody test to eliminate Hepatitis B carrier donors, and to identify donors with a history of viral Hepatitis, was known science by 1978. The HBc test was reported to be an effective surrogate test for both AIDS transmission and NANB Hepatitis carriers by 1982, yet no Defendant implemented this test until April 1984.

PARAGRAPH NO. 91 ANSWER: Bayer denies that it engaged in any unlawful agreement. Bayer denies that Cutter did not implement the HBc test until April, 1984. Bayer denies that HBc screening could do more than detect the presence of antibodies to the Hepatitis B virus. Bayer specifically denies that HBc screening was "highly effective" at screening donors. Bayer further states that HBc screening was not approved by the FDA as a surrogate test at the time referred to in plaintiffs' allegation, nor has it ever been approved for that purpose. Except as denied above, to the extent the matters set forth in Paragraph 91 of the Complaint are intended to constitute allegations of a defect, wrongdoing or a failure to exercise due care directed to Bayer and/or its predecessors, Bayer denies them. Bayer is without knowledge or

information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 91 of the Complaint.

92. Defendants used donors from predominantly homosexual donor centers, prisons, and inner city areas where the risk of IV drug abuse was high. After July 1982, when the results of this conduct culminated in reports of fatal immune suppression in three people with hemophilia who infused the product, this concert of action took on a more overt, active form.

PARAGRAPH NO. 92 ANSWER: Bayer admits that it processed plasma taken from human donors. Bayer denies that it obtained plasma from donors who were at high risk for drug abuse. Bayer denies that it engaged in any concert of action. Except as admitted or denied above, to the extent the remaining allegations in Paragraph 92 are intended to constitute allegations of a defect, wrongdoing or a failure to exercise due care directed to Bayer and/or its predecessors, Bayer denies them. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 92 of the Complaint.

93. By December 1982, the FDA demanded that Defendants stop using prisoners, donors from high risk areas for hepatitis and AIDS transmission, and known homosexuals. Rather than use good faith efforts to comply with the FDA requests, Defendants collectively argued for a far less onerous and less effective donor screening program. They jointly proposed a system comprised of educating the donor by posting a placard in the donor center stating who the risk groups for AIDS transmission were, and advising the donor that he would be deferred if he acknowledged he was a member of one of those groups. Later, he would be required to fill out a questionnaire in private. If he checked the box indicating he was in a high risk group, he would be permanently deferred.

PARAGRAPH NO. 93 ANSWER: The allegations in the first sentence in Paragraph 93 of the Complaint purport to refer to or describe FDA communications in December 1982. Such

communications are in writing and speak for themselves. To the extent the allegations in Paragraph 93 are inconsistent with the FDA's December 1982 communications, Bayer denies them. Bayer is without knowledge or information sufficient to form a belief as to the truth of the allegations in the second sentence in Paragraph 93 of the Complaint, except that to the extent those allegations are intended to constitute allegations of a defect, wrongdoing or a failure to exercise due care directed to Bayer and/or its predecessors, Bayer denies them.

94. At a January 6, 1983 meeting of Defendants' trade association, the Biological Section of the Pharmaceutical Manufacturer's Association ("PMA"), Defendants agreed not to implement highly effective HBc donor screening, instead selecting ineffective donor questionnaires that did little to screen out donors at high risk for AIDS transmission. Defendants further agreed to keep each other informed as to what the other was doing in order that a low standard of care was maintained. HBc testing had been strongly suggested by the CDC at the January 4, 1983 Public Health Service ("PHS") meeting. On January 14, 1983, Defendants acted jointly to persuade the National Hemophilia Foundation ("NHF") not to advocate surrogate testing for AIDS and Hepatitis C through implementation of the HBc test. Defendants persuaded the NHF that use of the HBc test was in the "R and D" stage and not practical to implement at that time.

PARAGRAPH NO. 94 ANSWER: Bayer admits that it participated in a PMA meeting in January 1983 at which the issue of surrogate testing (HBc screening) was considered. Bayer denies that it conspired with anyone and denies that any deferral evaluation of HBc testing by Bayer was proposed in bad faith or was improper. Bayer denies that HBc screening could do more than detect the presence of antibodies to the Hepatitis B virus. Bayer specifically denies that HBc screening was "highly effective" at screening donors. Bayer further states that HBc screening was not approved by the FDA as a surrogate test at the time referred to in plaintiffs'

allegation, nor has it ever been approved for that purpose. Except as admitted or denied above, to the extent the matters set forth in Paragraph 94 are intended to constitute allegations of a defect, wrongdoing or a failure to exercise due care directed to Bayer and/or its predecessors, Bayer denies any remaining allegations in Paragraph 94 of the Complaint. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 94 of the Complaint.

95. Defendants jointly agreed to oppose recall of the products beginning at the January 6, 1983 meeting at the Pharmaceutical Manufacturers' Association ("PMA"). Beginning with this meeting and continuing through at least July 19, 1983, Defendants met at various times to prepare a strategy to prevent the FDA from advocating a far-reaching recall of factor concentrate products. Defendants knew that due to their high risk donor populations, and their combining of these donors in pools of 5,000 to 40,000, that their products were contaminated with the AIDS agent. Nevertheless, Defendants acted in concert to lobby the FDA, to get the FDA to issue recommendations to limit recalls to circumstances in which an identified donor had died of AIDS within a specified time after the pooling of that donor's plasma. Defendants were well aware that plasma from contaminated asymptomatic donors were mixed in the plasma pools and contaminated virtually all lots. Defendants were successful in deferring any FDA Blood Products Advisory Committee ("BPAC") recommendation for a general recall of the product at the July 19, 1983 BPAC meeting. This joint action allowed the defendants to avoid ever recalling any product except when a donor died of AIDS.

PARAGRAPH NO. 95 ANSWER: Bayer denies that it engaged in any improper agreement or concert of action. Except as denied above, to the extent the remaining allegations set forth in Paragraph 95 are intended to constitute allegations of a defect, wrongdoing or a failure to exercise due care directed to Bayer and/or its predecessors, Bayer denies them. Bayer

is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 95 of the Complaint.

96. Defendants conducted a meeting on or about January 6, 1983 at the PMA, a major purpose of which was to decide on a unified strategy to deal with increasing knowledge of risk of AIDS. At the meeting Defendants agreed to postpone submitting any request to the FDA for permission to amend their warning labels or package inserts. They further agreed not to apply to the FDA for warnings enhancements until the other three companies agreed to make application for warning enhancements and to make the warnings similar in content. At the time of the meeting, Defendants had been informed by various reliable health authorities, including the PHS, that there was evidence of an association of risk between factor concentrate use and the transmission of AIDS.

PARAGRAPH NO. 96 ANSWER: Bayer admits that it participated in a PMA meeting in January 1983. Bayer denies that it entered into any improper agreements. To the extent the remaining matters set forth in Paragraph 96 are intended to constitute allegations of a defect, wrongdoing or a failure to exercise due care directed to Bayer and/or its predecessors, Bayer denies them. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 96 of the Complaint.

97. On December 13, 1983, Stephen Ojala, CUTTER's responsible head, documented by written memorandum that Defendants met and jointly agreed to propose a "study" of the HBc surrogate screening test, as a "delaying tactic" to avoid implementing the HBc test.

PARAGRAPH NO. 97 ANSWER: The allegations in Paragraph 97 of the Complaint purport to refer to or describe Defendants' internal communications. Such communications are in writing. To the extent allegations in Paragraph 97 are inconsistent with Defendants' internal communications, Bayer denies them. Bayer admits that in December 1983, certain

representatives of the plasma industry, BPAC and the FDA were present at a meeting where the creation of a Task Force to evaluate and study the utility of HBc testing was proposed. Bayer denies that it conspired with anyone and denies that the proposed evaluation of HBc testing by Bayer was proposed in bad faith or was intended to be an improper delaying tactic.

98. Thereafter, at various times throughout 1983-1985, Defendants attended meetings or otherwise communicated to assure joint efforts to avoid recalling product; to avoid warning patients of the true risk; to market product when sales dropped due to information in the lay press related to AIDS transmission through factor concentrates; to avoid recall of non-heat¬treated product after heat-treated products were available; to avoid implementation of the HBc test; and to coordinate a joint legal defense plan in anticipation of litigation from patients afflicted by AIDS through use of the products. Defendants also operated through trade organizations, such as ABRA and PMA, to issue public statements minimizing the risks of AIDS and Hepatitis C and overpromoting the benefits of factor concentrate, to carry out the above-mentioned goals of all Defendants.

PARAGRAPH NO. 98 ANSWER: To the extent they are directed to Bayer and/or its predecessors, Bayer denies the allegations in Paragraph 98 of the Complaint. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 98 of the Complaint.

99. All of the Defendants likely to have caused the harms to Plaintiffs are parties to this lawsuit and properly before the court.

PARAGRAPH NO. 99 ANSWER: The allegations in Paragraph 99 of the Complaint set forth conclusions of law to which no response is required. To the extent that a response is required, Bayer denies the allegations in Paragraph 99 of the Complaint.

100. The conduct of each and all of the Defendants, with respect to their Factor VIII and Factor IX

products and related plasma collection methods, was tortious.

PARAGRAPH NO. 100 ANSWER: The allegations in Paragraph 26 of the Complaint set forth conclusions of law to which no response is required. To the extent that a response is required, Bayer denies the allegations in Paragraph 100 of the Complaint.

101. The harm which has been caused to Plaintiffs resulted from the conduct of one, or various combinations of the Defendants, and, through no fault of the Plaintiffs, there may be uncertainty as to which one or combination of Defendants caused the harm.

PARAGRAPH NO. 101 ANSWER: To the extent they are directed to Bayer and/or its predecessors, Bayer denies the allegations in Paragraph 101 of the Complaint. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 101 of the Complaint.

102. The burden of proof should be upon each Defendant to prove that the Defendant has not caused the harms suffered by the Plaintiffs.

PARAGRAPH NO. 102 ANSWER: The allegations in Paragraph 102 of the Complaint set forth conclusions of law to which no response is required. To the extent that a response is required, Bayer denies the allegations in Paragraph 102 of the Complaint.

103. AHF was manufactured using the same fractionation method by all Defendants. As such, during the relevant years from 1975 until 1985, factor concentrates were a fungible product, and physicians prescribed the products interchangeably without regards to brand names of the drugs.

PARAGRAPH NO. 103 ANSWER: Bayer again denies that factor concentrates were manufactured. Bayer denies that Bayer's fractionation methods were the same as those used by the other Defendants. Bayer denies that factor concentrates were fungible or were, in all cases,

prescribed interchangeably. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 103 of the Complaint.

104. The factor concentrates manufactured by Defendants from 1975 until 1985 contained the same design flaws. They were all manufactured from paid donor plasma, which was at highest risk for Hepatitis B, Hepatitis C, and HIV viral transmission. In addition, the factor concentrate was made from large pools consisting of 5,000 to 40,000 paid donors, which further magnified the risk of viral transmission.

PARAGRAPH NO. 104 ANSWER: Bayer admits that from 1975 to 1985 it processed factor concentrates from pooled plasma from multiple donors; some of whom were compensated for the time they spent making donations. Bayer denies that those donors were at high risk for Hepatitis B and Hepatitis C. Bayer denies that factor concentrates were "designed" or manufactured. To the extent the remaining matters set forth in Paragraph 104 are intended to constitute allegations of a defect, wrongdoing or a failure to exercise due care directed to Bayer and/or its predecessors, Bayer denies them. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 104 of the Complaint.

105. None of the factor concentrate was virally inactivated during this time period. Therefore, all of the AHF carried a significant risk of viral transmission. In addition, all of Defendants' factor concentrate products were similarly misbranded. All of the products failed to warn of the known risks enumerated in this complaint.

PARAGRAPH NO. 105 ANSWER: Bayer denies the allegations in Paragraph 105 of the Complaint.

V. ANSWER TO ALLEGATIONS REGARDING TOLLING OF APPLICABLE

STATUTES OF LIMITATIONS

106. Any and all potentially applicable statutes of limitations have been tolled by Defendants' affirmative and intentional acts of fraudulent conduct, concealment, and misrepresentation, alleged above, which estop Defendants from asserting statutes of limitation. Such acts include but are not limited to intentionally covering up and refusing to disclose use of high risk plasma; sale of products abroad known to be contaminated; suppressing and subverting medical and scientific research; and failing to disclose and suppressing information concerning the risks of HIV and HCV transmission from Defendants' contaminated factor concentrate. For example, while the spread of AIDS in homosexuals and IV drug users became known to the FDA and the public, only Defendants knew that these very populations were the donors Defendants were targeting to obtain plasma for their factor concentrate products.

PARAGRAPH NO. 106 ANSWER: The allegations in Paragraph 106 of the Complaint state conclusions of law to which no response is required. To the extent that a response is required, Bayer denies the allegations in Paragraph 106 of the Complaint.

107. Defendants are estopped from relying on any statutes of limitation because of their fraudulent concealment and misrepresentation alleged above. Defendants were under a duty to disclose the risks of HIV and HCV transmission from their contaminated factor concentrate because this is nonpublic information over which they had exclusive control, because Defendants knew this information was not readily available to people with hemophilia like Plaintiffs' Decedent, and because this information was relevant to such people in deciding whether to use Defendants' factor concentrate.

PARAGRAPH NO. 107 ANSWER: The allegations in Paragraph 107 of the Complaint state conclusions of law to which no response is required. To the extent that a response is required, Bayer denies the allegations in Paragraph 107 of the Complaint.

108. Until very recently, Plaintiffs had no knowledge that Defendants were engaged in much of the wrongdoing alleged herein. Because of the fraudulent and active concealment of the wrongdoing by Defendants, including but not limited to deliberate efforts— which continue to this day—to give Plaintiffs the materially false impression that Defendants undertook all feasible safety precautions to reduce the risk of HIV and HCV transmission from their contaminated factor concentrate, Plaintiffs could not reasonably have discovered the wrongdoing any time prior to this time, nor could Plaintiffs have, as a practical matter, taken legally effective action given the unavailability, until very recently, of internal memoranda and other documents (as generally described herein) as evidence in support of Plaintiffs' claims. Defendants still refuse to admit and continue to conceal their wrongdoing, and therefore Defendants' acts of fraudulent concealment and misrepresentation continue through the present time.

PARAGRAPH NO. 108 ANSWER: Bayer denies the allegations in Paragraph 108 of the Complaint, except that Bayer is without knowledge or information sufficient to form a belief as to the truth of allegations in the first sentence in Paragraph 108 of the Complaint regarding what Plaintiffs allegedly knew or when they allegedly knew it.

VI. ANSWER TO ALLEGATIONS REGARDING CLAIMS FOR RELIEF

Answer to Plaintiffs' Wrongful Death and Survival Action Allegations

109. Plaintiffs incorporate by reference all previous paragraphs of this Complaint as if fully set forth here and further allege as follows:

PARAGRAPH NO. 109 ANSWER: Bayer incorporates by reference its responses to all preceding paragraphs as if fully set forth herein and further answers as follows:

110. Defendants marketed their Factor VIII and/or Factor IX blood products to and for the benefit of Plaintiffs and Plaintiffs' Decedent, and knew or had reason to know of the defects in their Factor VIII and/or Factor IX blood products, and that Plaintiffs and Plaintiffs' Decedent would use the blood products.

PARAGRAPH NO. 110 ANSWER: Bayer admits that it processed and distributed Factor VIII or Factor IX for the treatment of hemophilia. Except as admitted above, to the extent the matters set forth in Paragraph 110 are intended to constitute allegations of a defect, wrongdoing or a failure to exercise due care directed at Bayer and/or its predecessors, Bayer denies them. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 110 of the Complaint.

111. Defendants owed Plaintiffs and Plaintiffs' Decedent duties to exercise reasonable or ordinary care under the circumstances in light of the generally recognized and prevailing best scientific knowledge, and to produce the blood factor concentrate products in as safe a manner and condition as possible.

PARAGRAPH NO. 111 ANSWER: The allegations in Paragraph 111 of the Complaint set forth conclusions of law to which no response is required. To the extent that a response is required, and to the extent matters set forth in Paragraph 111 are intended to constitute allegations of a defect, wrongdoing or a failure to exercise due care directed at Bayer and/or its predecessors, Bayer denies them. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 111 of the Complaint.

112. Specific defects, as specified above in this Complaint, in the blood products, rendered them defective and unreasonably dangerous.

PARAGRAPH NO. 112 ANSWER: The allegations in Paragraph 112 of the Complaint set forth conclusions of law to which no response is required. To the extent that a response is required, and to the extent matters set forth in Paragraph 112 are intended to constitute allegations of a defect, wrongdoing or a failure to exercise due care directed at Bayer and/or its predecessors, Bayer denies them. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 112 of the Complaint.

113. Through the conduct described in the foregoing and subsequent paragraphs of this Complaint, the Defendants breached their duties to Plaintiffs' Decedent. Such breach exhibited a reckless disregard for the safety of others and willful and wanton conduct.

PARAGRAPH NO. 113 ANSWER: The allegations in Paragraph 113 of the Complaint set forth conclusions of law to which no response is required. To the extent that a response is required, and to the extent matters set forth in Paragraph 113 are intended to constitute allegations of a defect, wrongdoing or a failure to exercise due care directed at Bayer and/or its predecessors, Bayer denies them. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 113 of the Complaint.

114. As the direct, producing, proximate and legal cause and result of the Defendants' breach of their duties, Decedent died on or about March 31, 2007.

PARAGRAPH NO. 114 ANSWER: To the extent the allegations in Paragraph 114 of the Complaint are directed to Bayer and/or its predecessors, Bayer denies them. Bayer is

without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 114 of the Complaint.

115. As the direct, producing, proximate and legal cause and result of the Defendant's breach of their duties, Plaintiffs, individually and as a representatives of Decedent, have been injured and have incurred damages, including but not limited to medical and hospital expenses in the past, past physical and mental pain and suffering, and have suffered loss of financial support, goods and services, consortium, and the loss of familial and emotional love and support.

PARAGRAPH NO. 115 ANSWER: The allegations in Paragraph 115 of the Complaint set forth conclusions of law to which no response is required. To the extent that a response is required, and to the extent matters set forth in Paragraph 115 are intended to constitute allegations of a defect, wrongdoing or a failure to exercise due care directed at Bayer and/or its predecessors, Bayer denies them. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 115 of the Complaint.

116. Plaintiffs are therefore entitled to damages in an amount to be proven at trial, together with interest thereon and costs.

PARAGRAPH NO. 116 ANSWER: To the extent matters set forth in Paragraph 116 are intended to constitute allegations of a defect, wrongdoing or a failure to exercise due care directed at Bayer and/or its predecessors, Bayer denies them. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 116 of the Complaint.

117. Defendants' conduct, as alleged above, was malicious, intentional and outrageous and constituted willful and wanton disregard for the rights or safety of others. Such conduct was directed

specifically at Plaintiffs and Plaintiffs' decedents and was such as warrants an award of punitive damages.

PARAGRAPH NO. 117 ANSWER: The allegations in Paragraph 117 of the Complaint set forth conclusions of law to which no response is required. To the extent that a response is required, and to the extent matters set forth in Paragraph 117 are intended to constitute allegations of a defect, wrongdoing or a failure to exercise due care directed at Bayer and/or its predecessors, Bayer denies them. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 117 of the Complaint.

WHEREFORE, Bayer demands that the Court dismiss Plaintiffs' claims with prejudice, enter judgment in favor of BAYER, and award Bayer such other relief as the Court deem just and appropriate.

Second Defense

155. Bayer asserts that the claims made in Plaintiffs' Complaint are governed by the laws of the country or state (defined herein to include foreign and domestic states) in which Plaintiffs currently reside and not the law of Illinois. In any event, if Plaintiffs cannot recover in the jurisdiction in which they currently reside, comity requires that they be denied recovery in this Court.

Third Defense

156. The Complaint does not contain sufficient facts to constitute a legally cognizable claim against Bayer and/or its predecessors, and all claims against Bayer should be dismissed for failure to state a claim upon which relief may be granted.

Fourth Defense

157. All or part of the claims for relief contained in Plaintiffs' Complaint are barred by the applicable statute of limitations, repose or similar statutes, regulations or policies.

Fifth Defense

158. If Plaintiffs sustained the injuries or incurred the expenses as alleged, which is expressly denied, said injuries or expenses were directly and proximately caused by the negligence or fault of parties other than Bayer, whether named or unnamed in Plaintiffs' Complaint, over whom Bayer had no supervision or control and for whose actions and omissions Bayer has no legal responsibility. Plaintiffs' recovery, if any, therefore should be apportioned in accordance with the applicable law.

Sixth Defense

159. Plaintiffs' claim for relief is barred because Plaintiffs, directly or through their physicians, assumed the risk and were fully cognizant of all circumstances surrounding the utilization of any Factor VIII or Factor IX concentrates processed by Bayer and/or its predecessors.

Seventh Defense

160. The state of the medical and scientific knowledge, and the published literature and other materials reflecting the state of the medical art, at all times pertinent to this action, were such that Bayer and/or its predecessors neither knew nor could have known that its factor concentrates presented a foreseeable risk of harm to the Plaintiffs based on normal and expected usage.

Eighth Defense

161. Bayer's and/or its predecessor's Factor VIII and Factor IX concentrates were processed and distributed in accordance with directives and consistent with the regulations of the United States FDA and other applicable regulatory authorities and, therefore, any claim by Plaintiffs is barred by the doctrine of preemption.

Ninth Defense

162. Plaintiffs' Complaint fails to state a claim upon which relief can be granted against Bayer because any Factor VIII and Factor IX concentrates distributed by Bayer and/or its predecessors were in accordance with the applicable state-of-the-art, the state of scientific knowledge and all applicable regulations of the FDA and other applicable regulatory authorities, and distributed pursuant to the approval of the FDA and other applicable regulatory authorities.

Tenth Defense

163. Any Factor VIII and Factor IX concentrates Bayer and/or its predecessors prepared or supplied were derived from human blood and constituted a service and, accordingly, pursuant to applicable "blood shield statutes" and similar doctrines, Bayer is not liable under any theory of product liability.

Eleventh Defense

164. The claims of Plaintiffs fail because Plaintiffs have failed to take steps to mitigate damages, if any, and their recovery must be diminished accordingly.

Twelfth Defense

165. At all relevant times, Bayer's and/or its predecessor's Factor VIII or Factor IX concentrates were, under Federal law and the laws of the other relevant jurisdictions, only available or on the order of a licensed physician, and persons other than Bayer, including

Plaintiffs' treating physicians and health care personnel and institutions, stood in the position of learned intermediary between Bayer and Plaintiffs. The claims in the Complaint against Bayer accordingly are barred in whole or in part by the learned intermediary doctrine.

Thirteenth Defense

166. Plaintiffs' claims are barred, in whole or in part, by laches, waiver and/or estoppel.

Fourteenth Defense

167. The Northern District of Illinois is an improper and/or inconvenient venue for this action because this venue imposes oppressiveness and vexation on Bayer out of all proportion to Plaintiffs' convenience.

Fifteenth Defense

168. If Plaintiffs sustained the injuries or incurred the expenses as alleged, which is expressly denied, said injuries or expenses were caused by the unforeseeable alteration, improper handling, or other unforeseeable misuse of any Factor VIII and Factor IX concentrates Bayer and/or its predecessors prepared or supplied.

Sixteenth Defense

169. If Plaintiffs sustained any injuries or damages as a result of the matters alleged, such damages and injuries, if any, were contributed to and caused by the negligence or other wrongful conduct of persons whose conduct is imputed by law to Plaintiffs, constituting a bar to any recovery by Plaintiffs or, in the alternative, recovery, if any obtained, should be reduced to the extent the negligence of such other persons or parties was a cause of the injuries and damages.

Seventeenth Defense

170. Plaintiffs' claims are barred by the doctrine of *res judicata* and/or collateral estoppel.

Eighteenth Defense

171. Bayer specifically denies the existence of any implied warranties of merchantability and/or fitness. In the alternative, the warranty claims are barred by lack of privity and failure to provide reasonable and adequate notice of any breach of such warranties.

Nineteenth Defense

172. All factor concentrates prepared and provided by Bayer and/or its predecessors, including their labels and labeling, have been approved by the appropriate regulatory agencies pursuant to applicable statutes and regulations; approval and preparation of said factor concentrates was in compliance with all requirements pertaining to the preparation and/or distribution of such factor concentrates and was accomplished pursuant to acceptable standards of conduct.

Twentieth Defense

173. To the extent that Plaintiffs' claims are based on a theory providing for liability without proof of causation, the claims violate Bayer's rights under the United States Constitution and any applicable State constitutions.

Twenty-First Defense

174. Plaintiffs' Complaint fails to plead fraud with particularity as required by Rule 9(b), Federal Rules of Civil Procedure.

Twenty-Second Defense

175. Plaintiffs cannot state a claim with regard to warnings and labeling for prescription biologicals because the remedy sought by Plaintiffs is subject to the exclusive regulation of the FDA.

Twenty-Third Defense

176. This court should abstain from adjudicating Plaintiffs' claims relating to warnings and labeling in deference to the interpretation of regulations relating to prescription biological labeling by the FDA.

Twenty-Fourth Defense

177. Upon information and belief, each item of economic loss alleged in the Complaint was, or with reasonable certainty will be, replaced or indemnified in whole or in part by collateral sources.

Twenty-Fifth Defense

178. Plaintiffs did not detrimentally rely on any labeling, warnings or information concerning Factor VIII and Factor IX concentrates.

Twenty-Sixth Defense

179. Plaintiffs' claims are preempted by previously filed litigation in the United States and abroad.

Twenty-Seventh Defense

180. Plaintiffs' claims for punitive or exemplary damages are barred under any applicable State and/or federal law. Permitting recovery of punitive or exemplary damages in this case would contravene Bayer's constitutional rights as reserved by the Fifth, Seventh,

Eighth, and Fourteenth Amendments to the United States Constitution and other provisions of the United States Constitution and any applicable State constitutions.

Twenty-Eighth Defense

181. Because of the lack of clear standards, the imposition of punitive or exemplary damages against Bayer would be unconstitutionally vague and/or overbroad.

Twenty-Ninth Defense

182. With respect to Plaintiffs' demand for punitive or exemplary damages, Bayer specifically incorporates by reference any and all standards or limitations regarding the determination and enforceability of punitive or exemplary damages awards under the applicable law.

Thirtieth Defense

183. No act or omission of Bayer constituted intentional misconduct or gross negligence, nor was any act or omission of Bayer outrageous or with ill will, bad motive or reckless indifference to the interest of consumers, and Plaintiffs' Complaint fails to state a claim upon which relief can be granted for punitive or exemplary damages. Plaintiffs' Complaint seeks damages in excess of those permitted by law. Bayer asserts any statutory or judicial protection from punitive or exemplary damages that is available under the applicable law, and any award of punitive or exemplary damages is barred.

Thirty-First Defense

184. Any award of punitive or exemplary damages against Bayer is barred to the extent that it is inconsistent with any applicable standards and limitations set forth in *BMW of North America, Inc. v. Gore*, 517 U.S. 559, 134 L. Ed. 2d 809, 116 S. Ct. 1589 (1996), and *State Farm Mutual Automobile Insurance Co. v. Campbell*, 123 S. Ct. 1513 (2003).

Thirty-Second Defense

185. To the extent that Plaintiffs rely upon the doctrine of market share liability or alternative liability, Plaintiffs fail to state a claim upon which relief may be granted.

Thirty-Third Defense

186. Plaintiffs' Complaint fails to state a claim against Bayer upon which relief can be granted for several or joint and several liability.

Thirty-Fourth Defense

187. Plaintiffs' Complaint fails to join indispensable parties necessary for the just adjudication of this matter.

Thirty-Fifth Defense

188. Plaintiffs' Complaint fails to state a cause of action for fraudulent omission, concealment, or "willful", "malicious" or "outrageous" conduct against Bayer for which relief may be granted.

Thirty-Sixth Defense

189. Fraudulent misrepresentations made, if any, were not relied upon by Plaintiffs.

Thirty-Seventh Defense

190. At all times, Bayer and/or its predecessors, and anyone for whom it was responsible, fulfilled every duty imposed upon them by law and, as such, can have no liability.

Thirty-Eighth Defense

191. Plaintiffs' Complaint fails to state a claim upon which relief can be granted as to interest, costs and attorneys' fees.

Thirty-Ninth Defense

192. At all relevant times, Bayer's conduct was in compliance with applicable foreign regulations issued by the applicable foreign authorities, and Plaintiffs' recovery against Bayer is therefore barred.

Fortieth Defense

193. Plaintiffs' alleged injuries and damages, if any, were the result of an idiosyncratic reaction which Bayer could not reasonably foresee.

Forty-First Defense

194. The injuries and damages claimed by Plaintiffs, if any, resulted from an intervening or superseding cause and/or causes, and any act or omission on the part of Bayer was not the proximate and/or competent producing cause of such alleged injuries and damages.

Forty-Second Defense

195. The alleged injuries of Plaintiffs were the result of unavoidable circumstances, which could not have been prevented by anyone.

Forty-Third Defense

196. Plaintiffs failed to give timely notice of their breach of warranty claims, if any, and therefore are precluded from recovery.

Forty-Fourth Defense

197. Plaintiffs' claims are barred, in whole or in part, pursuant to the doctrine of primary jurisdiction; the FDA is charged with regulating biologics, including factor concentrates, and is specifically charged with determining the content of the warnings and labeling for biologics.

Forty-Fifth Defense

198. To the extent that Plaintiffs' claims are based on alleged misrepresentations or omissions made to the FDA, under federal law such claims are barred pursuant *Buckman v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001).

Forty-Sixth Defense

199. To the extent Plaintiffs attempt to seek equitable relief, they are not entitled to such relief because they have an adequate remedy at law.

Forty-Seventh Defense

200. Some of Plaintiffs' claims are barred in whole or in part by the First Amendment to the Constitution of the United States and/or the applicable constitution or equivalent legal document of any State whose laws might be deemed controlling in this case.

Forty-Eighth Defense

201. Plaintiffs' injuries and losses, if any, were proximately caused by their own failure to use factor concentrate in a reasonably foreseeable and intended manner, or in a manner consistent with the therapy's labeling and their claims are therefore barred.

Forty-Ninth Defense

202. If it is determined that a risk is inherent in factor concentrates, then such risk is outweighed by the benefits of factor concentrates.

Fiftieth Defense

203. To the extent that Plaintiffs' rely on the doctrine of failure to warn, they have failed to state a claim upon which relief may be granted.

Fifty-First Defense

204. In collecting plasma and processing and distributing Factor VIII and Factor IX concentrate, Bayer has undertaken to supply the public with an apparently useful and desirable medical therapy. The public interest and the availability of such therapies, as well as the Restatement of Torts, precludes liability for any risks resulting from such activities which were unavoidable given the state of human knowledge at the time those activities were undertaken.

Fifty-Second Defense

205. Plaintiffs' claims are barred to the extent laws or other programs within their own countries provide for financial compensation or assistance for Plaintiffs' alleged injuries.

Fifty-Third Defense

206. Bayer reserves the right to make a written election of credit for settlements under applicable law. Bayer further demands that its fault and/or responsibility be compared to other parties and non-parties to this suit as provided by any governing statutory or common-law scheme of comparative fault, comparative responsibility and contribution.

Fifty-Fourth Defense

207. Plaintiffs are not the real parties in interest or lack the capacity and/or standing to bring the claims asserted in the Complaint.

Fifty-Fifth Defense

208. Bayer adopts and incorporates by reference all defenses pleaded by other defendants except to the extent that they are inconsistent with Bayer's defenses pleaded in this Answer.

Fifty-Sixth Defense

209. Bayer has not knowingly or intentionally waived any applicable defenses, and asserts all defenses available under the law of the country in which Plaintiffs reside. Bayer reserves the right to amend its answer and separate and additional defenses to conform to such facts as may be revealed in discovery or otherwise.

PRAYER FOR RELIEF

WHEREFORE, Defendant BAYER CORPORATION prays for judgment as follows:

1. That Plaintiffs take nothing by virtue of the Complaint;

2. That if Plaintiffs are awarded damages, those damages be apportioned among all parties, persons and entities, and/or their agents, servants and employees whose conduct contributed to the claimed injuries and damages;

3. For Attorneys' fees and costs of suit incurred herein; and

4. For such other and further relief as the Court may deem just and proper.

Dated: August 11, 2008

Respectfully submitted,

By: /s/ Geoffrey Smith

Philip S. Beck
BARTLIT BECK HERMAN PALENCHAR & SCOTT
54 West Hubbard Street, Suite 300
Chicago, Illinois 60610
Telephone: (312) 494-4411
Facsimile: (312) 494-4440

Lindley J. Brenza
Kaspar Stoffelmayr
BARTLIT BECK HERMAN PALENCHAR & SCOTT
1899 Wynkoop Street, 8th Floor
Denver, Colorado 80202
Telephone: (303) 592-3130

Facsimile: (303) 592-3140

Duncan Barr
O'CONNOR, COHN, DILLON & BARR
2405 16th Street
San Francisco, California 94103
Telephone: (415) 281-8888
Facsimile: (415) 503-4117

Geoffrey R. W. Smith
GEOFFREY SMITH, PLLC
1350 I Street NW Suite 900
Washington, District of Columbia 20005
Telephone: (202) 625-1224
Facsimile: (202) 333-1637

DEMAND FOR JURY TRIAL

Defendant Bayer Corporation demands a trial by jury on all issues stated.

Dated: August 11, 2008

Respectfully submitted,

BY: /s/ Geoffrey Smith

Philip S. Beck
BARTLIT BECK HERMAN PALENCHAR & SCOTT
54 West Hubbard Street, Suite 300
Chicago, Illinois 60610
Telephone: (312) 494-4411
Facsimile: (312) 494-4440

Lindley J. Brenza
Kaspar Stoffelmayr
BARTLIT BECK HERMAN PALENCHAR & SCOTT
1899 Wynkoop Street, 8th Floor
Denver, Colorado 80202
Telephone: (303) 592-3130
Facsimile: (303) 592-3140

Duncan Barr
O'CONNOR, COHN, DILLON & BARR
2405 16th Street
San Francisco, California 94103
Telephone: (415) 281-8888
Facsimile: (415) 503-4117

Geoffrey R. W. Smith
GEOFFREY SMITH, PLLC
1350 I Street NW Suite 900
Washington, District of Columbia 20005
Telephone: (202) 625-1224
Facsimile: (202) 333-1637

CERTIFICATE OF INTERESTED ENTITIES OR PARTIES

Pursuant to Civil L.R. 3.2, the undersigned certifies that the following listed persons, associations of persons, firms, partnerships, corporations (including parent corporations) or other entities (i) have a financial interest in the subject matter in controversy or in a party to the proceeding, or (ii) have a non-financial interest in that subject matter or in a party that could be substantially affected by the outcome of this proceeding.

Name	Type of Interest
Bayer Corporation 100 Bayer Road Pittsburgh, Pennsylvania 15205-9741	Party
Bayer AG 51368 Leverkusen Germany	Parent Corporation

Dated: August 11, 2008

Respectfully submitted,

BY: /s/ Geoffrey Smith

Philip S. Beck
BARTLIT BECK HERMAN PALENCHAR & SCOTT
54 West Hubbard Street, Suite 300
Chicago, Illinois 60610
Telephone: (312) 494-4411
Facsimile: (312) 494-4440

Lindley J. Brenza
Kaspar Stoffelmayr
BARTLIT BECK HERMAN PALENCHAR & SCOTT
1899 Wynkoop Street, 8th Floor
Denver, Colorado 80202
Telephone: (303) 592-3130
Facsimile: (303) 592-3140

Duncan Barr
O'CONNOR, COHN, DILLON & BARR
2405 16th Street
San Francisco, California 94103
Telephone: (415) 281-8888
Facsimile: (415) 503-4117

Geoffrey R. W. Smith
GEOFFREY SMITH, PLLC
1350 I Street NW Suite 900
Washington, District of Columbia 20005
Telephone: (202) 625-1224
Facsimile: (202) 333-1637

CERTIFICATE OF SERVICE

I hereby certify that on the 11th day of August 2008, I filed the foregoing pursuant to the procedures for electronic filing of documents for the United States District Court for the Northern District of Illinois and that I also deposited a copy of same in the United States mail postage prepaid bearing first class addressed as below:

Elizabeth J. Cabraser LIEFF, CABRASER, HEIMANN & BERNSTEIN 275 Battery Street, 30th Floor San Francisco, CA 94111-3399	***Attorneys for Plaintiff*** **LIAISON COUNSEL FOR MDL PLAINTIFFS** Tel: (415) 956-1000 Fax: (415) 956-1008
Kevin J. Stack KNAPP PETERSEN & CLARKE 500 North Brand Blvd., 20th Floor Glendale, California 91203-1904	**COUNSEL FOR ALPHA THERAPEUTIC CORPORATION** Tel: (818) 547-5000 Fax: (818) 547-5329
Rick Berkman DECHERT LLP Cira Center 2929 Arch Street Philadelphia, PA 19104-2857	**COUNSEL FOR BAXTER HEALTHCARE CORPORATION** Tel: (215) 994-4000 Fax: (215) 655-2684
Sara Gourley SIDLEY AUSTIN LLP One South Dearborn Chicago, Illinois 60603	**COUNSEL FOR ARMOUR PHARMACEUTICAL COMPANY, AVENTIS BEHRING LLC, AVENTIS INC.** Tel: (312) 853-7000 Fax: (312) 853-7036

/s/ Geoffrey Smith